ditorial
amlanivimab for the
reatment of COVID-19

The COVID Vaccine is here. What this means for you.

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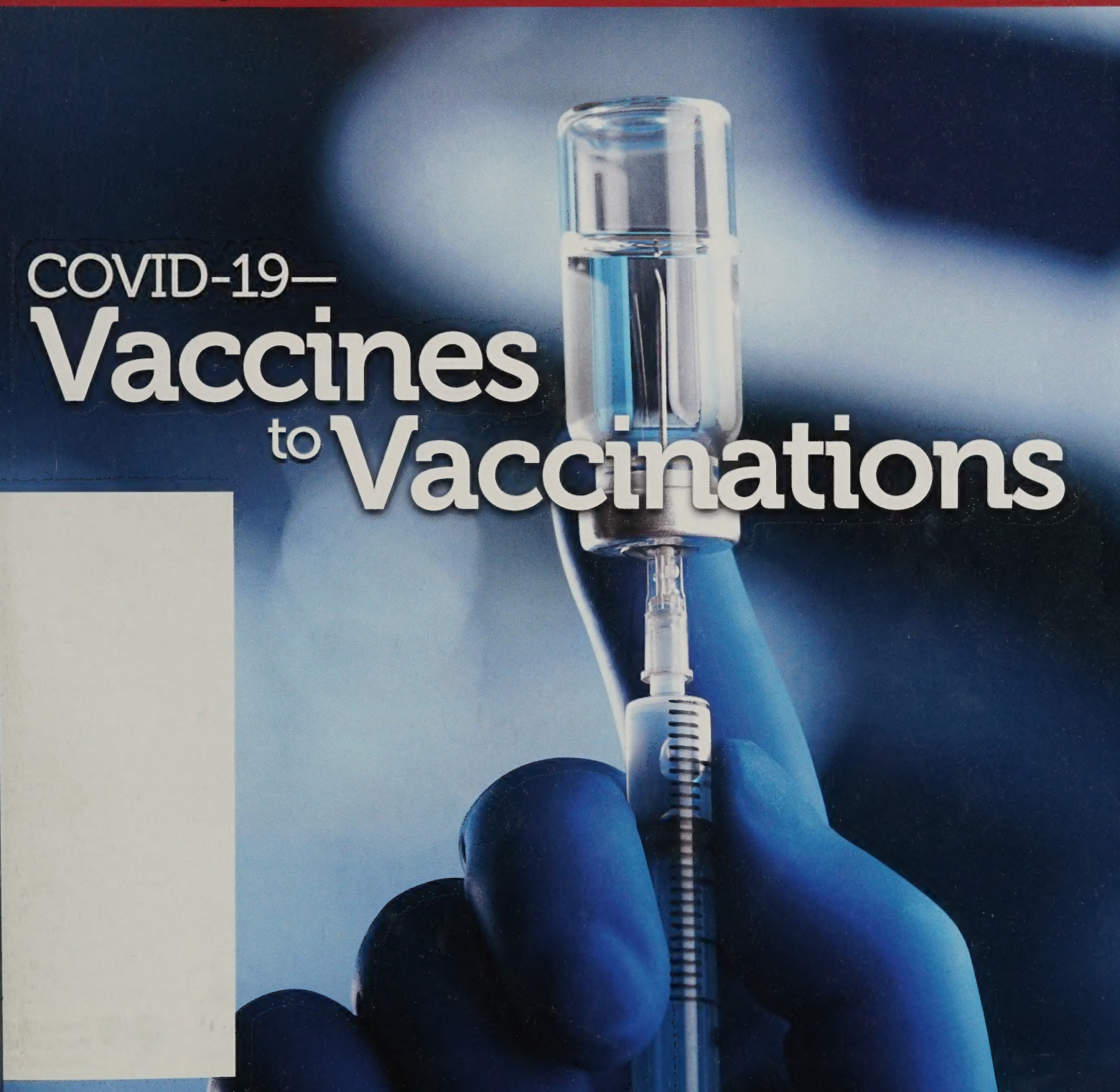
Maryland Pharmacist

WINTER 2021



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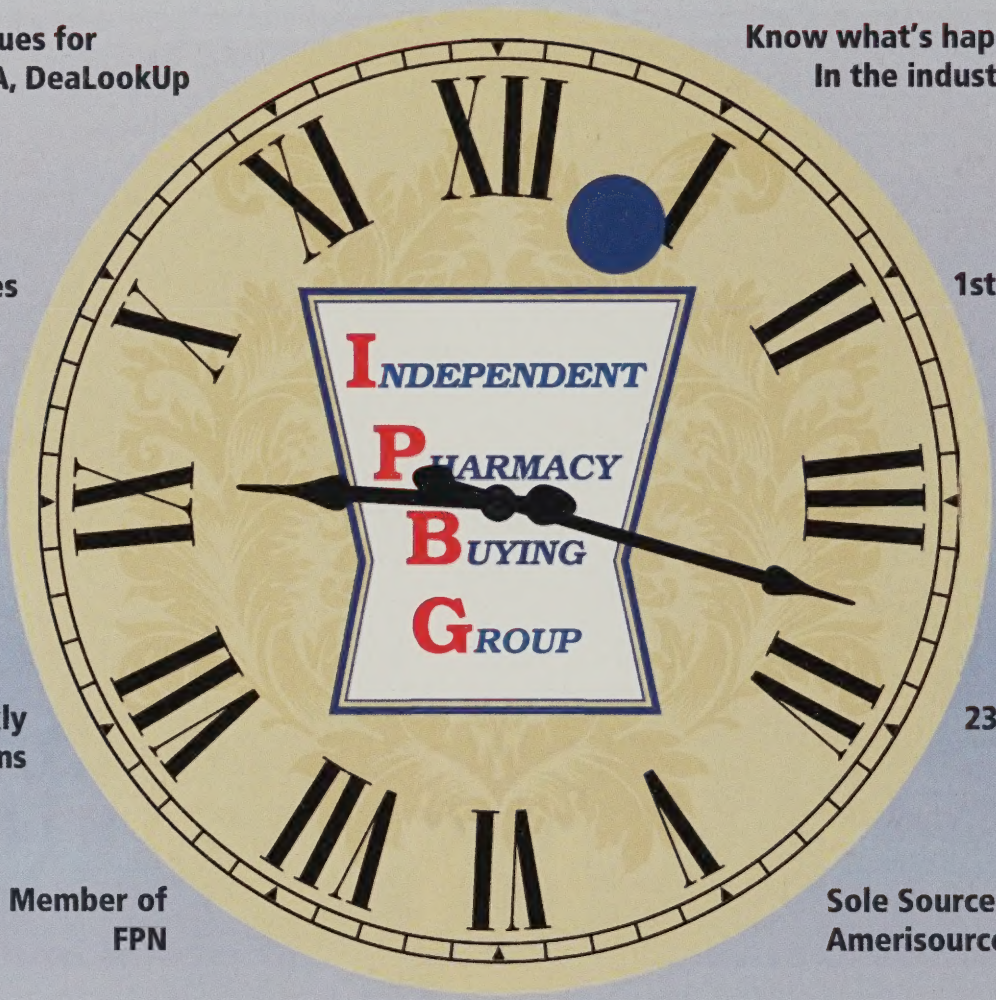

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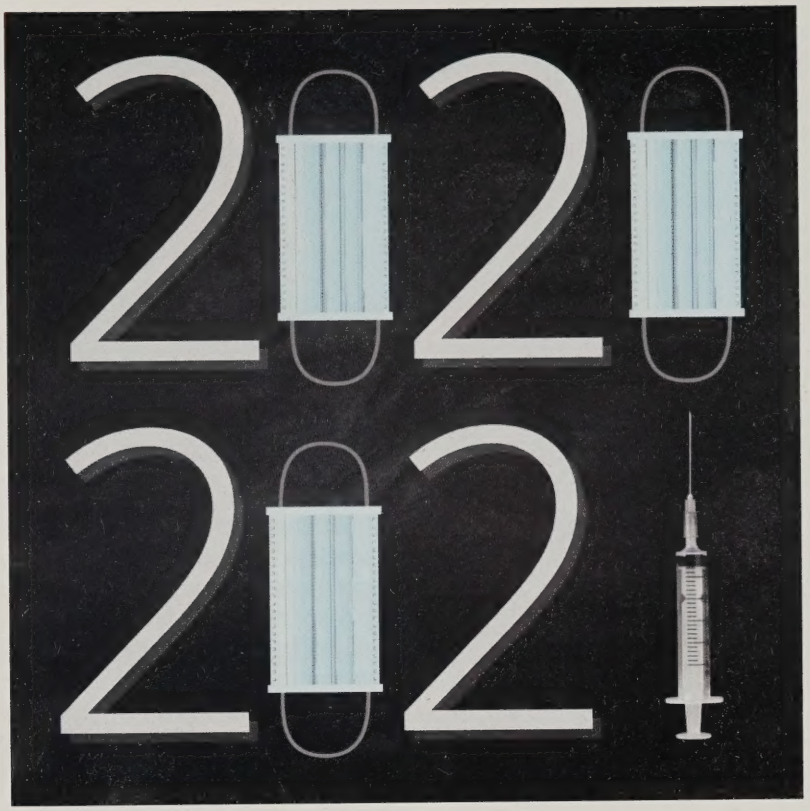
The COVID Vaccine is Here.

As Maryland moves into the 1C phase, what you need to know to help your patients and administer the vaccine.



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President's Pad

Each new year brings with it the promise of a fresh start and a chance to make positive changes, whether through big resolutions or small changes that you hope will make this year better than the last. For healthcare providers across the world, this year also brings hope that we are turning the corner in the COVID-19 pandemic through the promise of newly approved vaccines. I am thankful that national leaders and Governor Hogan recognized our importance to this process and included pharmacy staff in the first phase of vaccination. If you have not already gotten your vaccines, I encourage you to contact your county's health department for clinics in your area and share the information with your coworkers.

As Pharmacists and Pharmacy Technicians, we can play a key role in protecting our patients and wider communities through vaccination administration and education. As more vaccine supply becomes available, many of you will be able to help immunize first responders, healthcare providers, seniors, and essential workers. If you or coworkers are interested in doing more to help, I highly recommend you consider participating in Maryland Responds, our state's Medical Reserve Corps. This organization provides the opportunity for both clinical and non-clinical residents the chance to provide services during a disaster or emergency situation. Currently, that means staffing immunization clinics by filling roles such as administrative duties, filling syringes, vaccine administration, and patient monitoring after vaccination. As a volunteer, you can choose what events you support, both by selecting the county or counties you are willing to travel to and by individual event. I know every one of us is busy, but even helping at one or two events in your own county would help your local health department colleagues who are already working tirelessly to protect those most at risk. To register for Maryland Responds, visit https://mdresponds.health.maryland.gov/ to provide your information and complete the online orientation training.

As Pharmacists and Pharmacy Technicians, we can play a key role in protecting our patients and wider communities through vaccination administration and education.

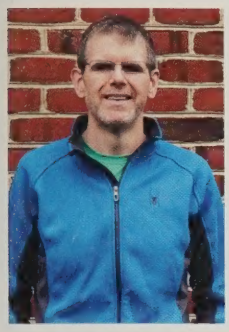
As one of the most trusted and accessible healthcare providers, we can also have a positive impact on our communities through education. As a profession, this need is not new to us. We have been working to dispel myths about vaccines for many years, while simultaneously teaching patients how vaccination not only protects each patient but those around them through building herd immunity. As with any new medication, there will be skepticism about the safety and efficacy of these new vaccines. I encourage each of you to continue to educate and spread hope not only your patients through your work, but also leverage your social network to share how you are helping to end the pandemic through getting your own vaccination and supporting vaccination in your community.

My best wishes to you for health and happiness in the upcoming year, and a sincere thank you for the amazing work you are doing to keep Maryland communities healthy.

Kerry Cormier

Kerry Cormier, PharmD
MPhA President 2020-2021

Member Mentions & News You Can Use



Congratulations to MPhA Member Brian Hose!

2020 brought lots of changes, here's one we can celebrate and take some inspiration on how we can all take better care of ourselves. Brian Hose, MPhA Past President, lost 100lbs since March 2020! In this short Pharmacy Resident podcast (15mins) he talks about his journey and shares the commitments he made that facilitated the change. https://bit.ly/3pssjHY. ●

Maryland Prescription Drug Affordability Board Announces New ED

The Maryland Prescription Drug Affordability Board announced the selection of MPhA member Andrew York, Pharm.D., J.D., as its Executive Director. Dr. York, who will formally assume the role on January 20, 2021, will serve as the Board's first Executive Director. Congratulations Andrew!

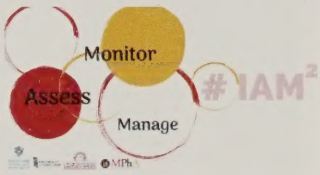
2-1-1 Maryland

2-1-1 Maryland connects Marylanders to the health and human services they need to achieve a more stable life for themselves and their families. 2-1-1 is an easy to remember telephone number that gives Marylanders access to information about resources and services they need to thrive.

https://211md.org/

And visit https://211md.org/211provider-md-mental-health- for assistanced with substance abuse

MPhA Foundation Receives Cardinal Health Foundation Grant



MPhA Foundation received a grant from the Cardinal Health Foundation to support the pharmacists' role in optimal prescribing for pain management. Maryland was one of five states picked to participate in the national project. Our effort is a collaboration between MPhA and the three schools of pharmacy in Maryland. The project team includes MPhA Executive Director, Aliyah N. Horton and Dr. Cherokee Layson-Wolf (UMB), Dr. Ray Weber (NDMU) and Dr. Richard DeBenedetto (UMES).

The project strives to normalize the collaboration between pharmacists, prescribers, and patients to ensure the safest use of opioids for pain management. The effort has included stakeholder outreach & engagement with practitioner and patient advocacy groups in Maryland with the goal of hosting joint activities focused on best practices to effectively implement CDC pain management prescribing guidelines.

The team is also collaborating with the Prescription Drug Monitoring Program to do data benchmarking related to changes in prescribing/dispensing patterns for (non-oncology or hospice) patients with an opioid prescription that is greater or equal to an average daily dose of 90MME of opioids; and those with an overlapping opioid and benzodiazepine prescription. We are looking to measure decline in these rates as a result of our outreach efforts. We have also launched a revamped the social media campaign #IAM2 (I Assess Monitor Manage) to demonstrate that patients, prescribers and pharmacists all have an important role in addressing pain management.

What can you do to support this work?

1. When you see the images and information about #IAM2 on your social media feeds, please like and share with your friends and colleagues.
2. Visit the project resource page on the MPhA website at www.marylandpharmacist.org/page/painmanagement
3. Be sure to sign the pledge that I am, too (IAM2) doing my part!

If you would like to be involved implementing the next phase of this project, a multidisciplinary CE/CME, please contact aliyah.horton@mdpha.com. ●

MPhA Welcomes OUR NEWEST MEMBERS

MARYLAND PHARMACISTS ASSOCIATION

Welcome to MPhA: If you meet these new members, please welcome them to the MPhA Pharmily and be sure to invite them to join a committee or attend a networking event!

Connected

Kaitlin Landolf – Severn
Kristine Parbouni – Ellicott City
Shalin Patel – Laurel
Thomas Laudon – Baltimore

Engaged

Chinelo Nriezedi – Fort Washington
Jami Butz – Lutherville

Informed

Angela Kim
Ashenafi Lemma – Ellicott City
Cathie Smith – Delaware
Jeffrey Kukel – Berlin
La Toya Toombs – Silver Spring
Ralph Dove – Silver Spring
Sheryl Nwankwo
Tom Evan – Fallston
Tselaine Smith – Bowie
Whitney Behrend – Elkridge
William LeGalle – Worton
Yasmine Amibarg – Silver Spring

Students

Achafack Crystelle, Manassas – NDU
Adebola Ondunsi, Reisterstown – UMES
Alyssa Reese, Crisfield – UMES
Anyelis Rosario, Harrison – UMB
Ashwini Pradhan, Glen Burnie – NDU
Bela Pandya, Pasadena – UMB
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Elizabeth Alvarez, Silver Spring – NDU
Eunice Nam, Ellicott City – UMB
Gabriela Torres, Baltimore – NDU
Isaac Agugoesi, Baltimore – NDU
Ishraat Jahan, Ellicott City – UMB
Jonah Ho, Gaithersburg – UMB
Josely Ann Rodriguez-Rios, San Juan – UMB
Kathryn Henderson, Baltimore – NDU
Keara Lopaz, Baltimore – UMB
Kevin Young, Princess Anne – UMES
Krystal Santiago, Baltimore – NDU
Laura Lugo, Baltimore – NDU
Lauren DiFacol, Towson – NDU
Laurie Cepeda, Baltimore – UMB
Lillian Weldon, Baltimore – NDU
Lyudmila Ashurova, Baltimore – UMB
Mahboubeh Hanaee, Baltimore – UMB
Mahsa Razavi, Monrovia – NDU
Mariam Momani, Baltimore – UMB
Modupe Kusoro, Baltimore – UMB
Mohammad Semeti, Philadelphia – Temple University
Mujin Kim, Baltimore – UMB
Nancy Oniovosa, Randallstown – NDU
Paola Mudafort, Baltimore – UMB
Rachel Large, Washapreague – UMES
Rebecca Bemadel, Baltimore – UMB
Rebekah Torchon, Salisbury UMES
Rose Dominic Sabastian, Nottingham – NDU
Rose Kostakis, Nottingham – NDU
Sanis Ali, Columbia – UMB
Sehara Hill, Princess Anne – UMES
Shannon Weathers, Columbia – UMB
Stephanie Jackson, Millersville – NDU
Sung Jeong, Columbia – UMB
Taylor Martin, Hurlock – UMES
Vivian Ndah, Fruitland – UMES
Yijie Cheng, Fruitland – UMB
Zachary Becouvarakis, Hampton – UMES

The COVID Vaccine is Here

As of February 3, 2021, Maryland providers have administered 565,131 COVID-19 vaccines, and 70.4% of all first doses have been given. The average daily rate of shots administered is 21,936—a 64% increase over the last two weeks. Maryland has entered the 1C phase of the vaccine rollout and plans to open a series of mass vaccination clinics on Friday, February 5. The first mass sites are set to open at the Baltimore Convention Center and Six Flags America in Prince George's County.

MPhA encourage pharmacists to review information on the Maryland Department of Health website, the CDC's COVID-19 Vaccination page, and the Immunization Action Coalition (IAC) COVID-19 webpage. All three sites are updated frequently and contain additional information.

MDH: https://coronavirus.maryland.gov/
CDC: https://www.cdc.gov/vaccines/covid-19/index.html
IAC: https://www.immunize.org/covid-19/

*Data pulled from the Maryland Department of Health website as of Wednesday, February 3, 2021. Please visit https://coronavirus.maryland.gov/ for current data.

Application of U.S. HHS Prep Act Amendments

The U.S. Department of Health and Human Services (U.S. HHS) issued amendments and guidance under the PREP Act that permit expanded immunization authority during the federally-declared public health emergency, if all requirements are met. In conjunction with state statues and requirements set by U.S. HHS, application in MD permits:

- Pharmacists ordering and administering ACIP-recommended and COVID-19 vaccines for ages 3+ without a prescription
- Interns administering ACIP-recommended and COVID-19 vaccines for ages 3+ under the supervision of a pharmacist
- Certified technicians administering ACIP-recommended to ages 3-18 and COVID-19 vaccines to anyone of any age under the supervision of a pharmacist

Continued on page 10

Editorial

Bamlanivimab for the Treatment of COVID-19

Isabel Baik, Pharm D Candidate 2021
University of Maryland School of Pharmacy

Sophia Pathan, PharmD, BCPS, Clinical Pharmacist, Critical Care and Surgery Pharmacy,
The Johns Hopkins Hospital

The authors have no conflicts of interest to disclose.

Coronavirus disease (COVID-19) is an infectious disease caused by a severe acute respiratory syndrome coronavirus also known as SARS-CoV-2.[1] The recent increase in COVID-19 cases and deaths has prompted the Food and Drug Administration (FDA) to issue emergency use authorizations (EUA) for new medications to treat COVID-19. Under the Federal Food, Drug, and Cosmetic Act (FD&C Act) section 564, the FDA Commissioner may allow unapproved medical products be used during public health emergencies when there are no approved, available alternatives.[2] On November 9, 2020, the FDA issued an EUA permitting the use of the unapproved investigational product bamlanivimab for COVID-19 treatment. The NIH COVID-19 Treatment Guidelines Panel reviewed the available evidence on bamlanivimab and determined there is insufficient data for or against the use of bamlanivimab as outpatient treatment in mild to moderate COVID-19 cases, recommending that bamlanivimab should not be considered as standard of care due to the lack of long-term efficacy data.[3]

Bamlanivimab (LY-CoV555) is an investigational neutralizing IgG1 monoclonal antibody that is directed against the spike protein of SARS-CoV-2.[4] It should only be used for the treatment of mild to moderate COVID-19 in non-hospitalized patients. The safety and efficacy of bamlanivimab is based on data from an ongoing, adaptive Phase II trial, *SARS-CoV-2 Neutralizing Antibody LY-CoV555 in Outpatients with Covid-19* (BLAZE-1). BLAZE-1 is a randomized, double-blind, placebo-controlled trial conducted at 41 centers across the United States.[5] This initial portion of the trial randomly assigned 452 low-risk patients to receive a single intravenous infusion of bamlanivimab at doses of 700 mg (N=101), 2800 mg (N=107), 7000 mg (N=101), or placebo (N=143).[5] By day 11, the data revealed a mean decrease from baseline in log viral load of 3.81 (baseline mean = 6.36; day 11 mean = 2.56) amongst a majority of patients including those in the placebo group.[5] However, the 2800 mg dose was the only one to show evidence of accelerated viral clearance, the primary endpoint of the study.[4] Despite studying three different doses, the EUA issued for bamlanivimab 700 mg dose due to a flat exposure-response curve for efficacy identified between the various doses.[6] Additionally, for patients at high risk for severe disease progression, average rates of hospitalizations occurred in 3% of bamlanivimab-treated patients compared to 10% in placebo-treated patients.[4] The interim analysis of BLAZE-1 indicated patients who received bamlanivimab had fewer hospitalizations and emergency department visits in addition to a lower symptom burden than those who received placebo.

Bamlanivimab is authorized for use in patients who are COVID-19 positive, are at least 12 years of age, weigh at least 40 kilograms, and are at high risk for progression to severe COVID-19 and/or hospitalization.[4] Refer to Table 1 for characteristics that are considered high risk.[7] Bamlanivimab is not authoritized for use in patients who are hospitalized or those who require oxygen therapy or mechanical ventilation. This is based on data from the clinical trial, *Therapeutics for Inpatients with COVID-19* (ACTIV-3), which was discontinued early for futility due to lack of clinical significance in hospitalized COVID-19 patients.[8] A single 700 mg dose of bamlanivimab should be administered over at least 60 minutes via intravenous infusion as soon as possible after positive COVID-19 test results and within 10 days of symptom onset. Clinical monitoring for hypersensitivity or infusion-related reactions is required for one hour after completion of the infusion. The most commonly reported adverse effects are nausea, vomiting, diarrhea, dizziness, headache, and infusion-reactions. In addition, the preparation of the intravenous admixture is stable for just 7 hours at room temperature or 24 hours under refrigeration, both including infusion time. Ensuring access to the treatment may also pose a challenge, as bamlanivimab is allocated by the federal government

to states, territories, and federal entities on a weekly basis.[9] Allocations are currently limited and in Phase II, which include expanded distribution from hospitals and hospital-affiliated locations to additional outpatient facilities, requiring patients to set up appointments at outpatient infusion centers, which are often not set up for urgent referrals and are populated with highly immunocompromised patients.

As more data emerges about the safety and effectiveness of the investigational therapy, the role of bamlanivimab in the treatment of COVID-19 patients may change. Because BLAZE-1 is an adaptive trial, the next phase of the study is still ongoing and will be comparing bamlanivimab in combination with a second antibody to bamlanivimab alone or placebo. Based on the current conditional recommendations from the FDA and NIH, the use of bamlanivimab is ultimately dependent on the informed decision of the patient. As recommended by the IDSA guideline panel, at this time, bamlanivimab is a reasonable treatment option if the patient places high value on uncertain benefits and less value on uncertain adverse events.[10] Further clinical trial data will be vital in understanding the place in therapy for bamlanivimab in treating patients with COVID-19.

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Table 1. Criteria of High-Risk Patients

High risk is defnited as patients who meet at least one of the following criteria:

- Have a body mass index (BMI) ≥ 35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥ 65 years of age
- Are ≥ 55 years of age AND have
  - Cardiovascular disease, OR
  - Hypertension, OR
  - Chronic obstructive pulmonary disease/other chronic respiratory disease
- Are 12-17 years of age AND have
  - BMI ≥ 85th percentile for their age and gender based on CDC growth charts, OR
  - Sickle cell disease, OR
  - Congenital or acquired heart disease, OR
  - Neurodevelopmental disorders (i.e. cerebral palsy), OR
  - A medical-related technological dependence (i.e. tracheostomy, gastrostomy, or positive pressure ventilation not related to COVID-19), OR
  - Asthma, reactive airway or chronic respiratory disease that requires daily medication for control

COVID-19 Vaccine continued from page 7

U.S. HHS has clarified that pharmacists and interns need to meet state statute to immunize in accordance with the U.S. HHS amendments. Pharmacists and interns do NOT need to have 20 hours of training.

Phased Allocation

Due to initial limited supply of COVID-19 vaccine, the vaccine will be available to certain populations in a phased approach. The phases are determined by CDC's ACIP and the Maryland Department of Health The following individuals are eligible for COVID-19 vaccination in conjunction with the vaccine EUA. If an individual does not meet one of the criteria below, they are not currently eligible for vaccination.

Being Vaccinated if You are Eligible: The local health departments will coordinate vaccine efforts within their communities. They will collaborate with local vaccine providers and identify health care workers that need the vaccine. DHS will support all local health departments in this effort. If local health departments need assistance to vaccinate healthcare providers, the state may provide additional resources, such as vaccination teams, to help fill the gaps.

At this time this journal went to print, vaccinations are only available through hospitals and local health departments statewide—contact providers to schedule your appointment. Vaccinations are appointment-only. Learn more at coronavirus.maryland.gov/pages/vaccine.

Send MPhA Your COVID-19 Vaccination Pictures!

Send us pictures, videos and stories of you receiving, preparing, or administering the vaccine, or a picture of you with your bandage on after you receive your vaccine. Photos may be shared on MPhA's social media pages to promote the COVID-19 vaccine and the role pharmacy professionals are playing in this effort. Send pictures, videos and stories to admin@mdpha.com or tag us on social media.

Phase	Definition according to MDH	When you can begin vaccinating
1A	All licensed, registered, and certified healthcare providers; nursing home residents and staff; law enforcement, and firefighters, EMS, and other first responders; correctional healthcare staff and officers; and front line judiciary staff.	Now
1B	Maryland residents who are 65 years and older; Marylanders in assisted living, independent living, developmental disabilities/ behavioral health group homes, and other congregate facilities; high-risk incarcerated individuals; continuity of government vaccinations; and education, including K-12 teachers, support staff, and child care providers.	Now
1C	Public health and safety workers not covered in Phase 1A; and essential workers in lab services, food/agriculture production, manufacturing, the U.S. Postal Service, public transit, and grocery stores	Now
Phase 2	Adults 16-64 at increased risk of severe COVID-19 illness due to comorbidities; essential workers in critical utilities, transportation, logistics, infrastructure, food service, etc; and incarcerated adults. Approximately 1.1 million individuals	TBD
Phase 3	General population, including healthy adults ages 16-64. Approximately 4 million individuals	TBD

Continuing Ed

You Can Make a Difference, You Can Help a Patient Stop Smoking

A Focus on Patients with Cardiovascular Disease

Kristin Watson, Pharm D, BCCP
Associate Professor, Department of Pharmacy Practice and Science
ATRIUM Cardiology Collaborative
University of Maryland School of Pharmacy

Qiwei Lin, BS; Pharm D Candidate 2022, University of Maryland School of Pharmacy

The authors have no conflicts of interest to disclose.

Learning Objectives

At the conclusion of this activity, the pharmacist will able to:

1. List steps that should be taken during each encounter with a patient who smokes.
2. Distinguish between smoking cessation treatment options — bupropion sustained release, nicotine replacement, and varenicline — regarding mechanisms of action, efficacy, and tolerability profiles in patients with cardiovascular disease.
3. Apply available evidence to define the role of bupropion sustained release, nicotine replacement, and varenicline for smoking cessation for a given case involving a patient with cardiovascular disease.
4. Provide smoking cessation eduation to a patient with cardiovascular disease.

Keywords

Nicotine, Cardiovascular disease, Bupropion, Smoking cessation, Tobacco, Varenicline

Introduction

Tobacco use has been well established as a major and modifiable risk factor for myocardial infarction and stroke. Smoking cigarettes is the most common form of tobacco use; however, there is a rise in the use of electronic cigarettes (e-cigarettes), cigars, hookah, cigarillos, and filter cigars.[1] The benefits of smoking cessation are seen within minutes of quitting (Table 1). Despite the known risks with continued smoking and benefits of quitting, providing assistance for quitting and follow-up occurs in less than 50% of primary care visits.[2,3] A recent report from the United States Surgeon General noted that lack of time, resources, and reimbursement for smoking cessation services limits the ability to provide this type of support to patients.[4] The National Institute Health Survey report has shown that, only 57.2% of smokers received advice to stop from a healthcare provider within the prior year.[5]

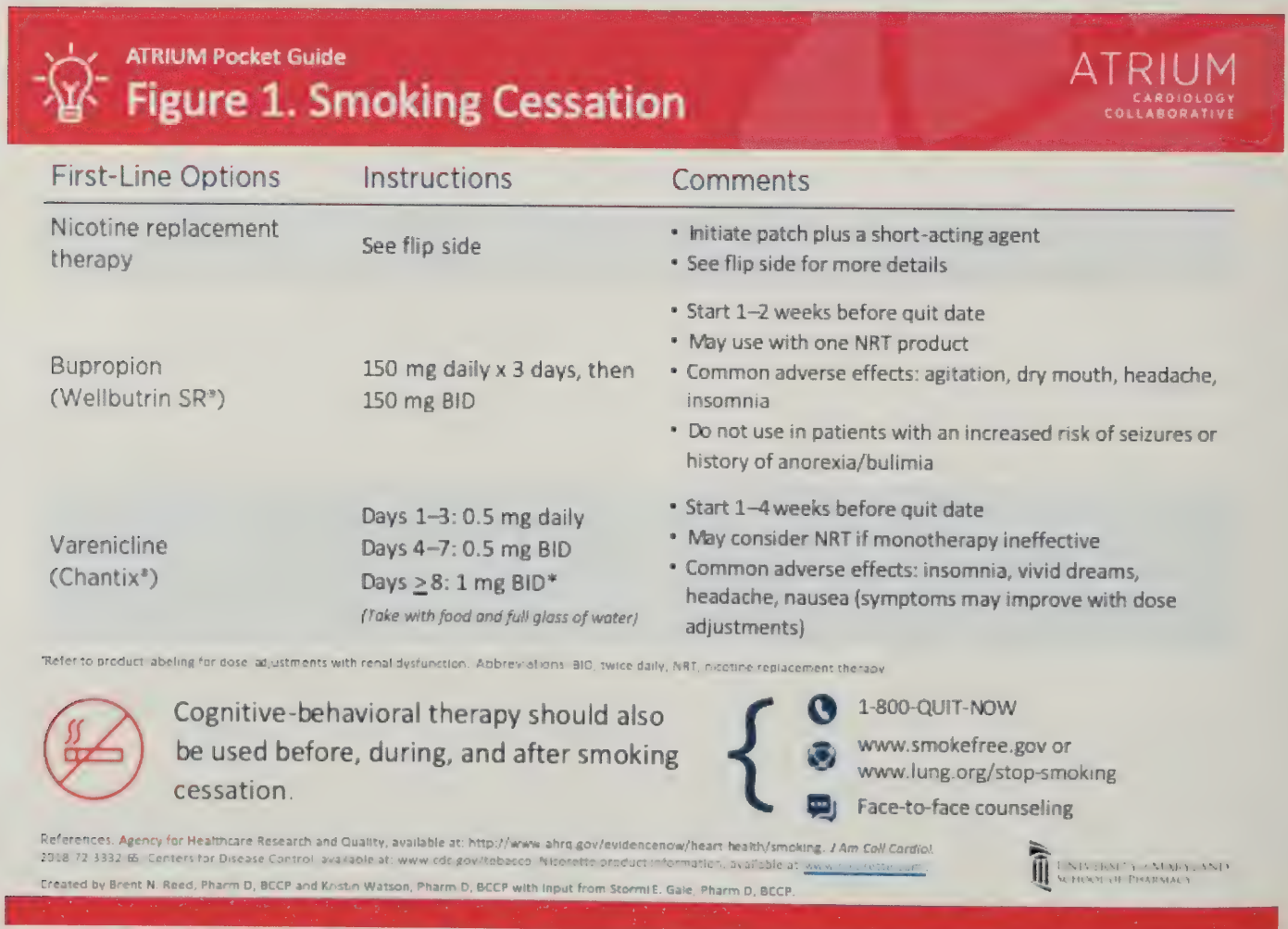
Pharmacists can play an integral role in assisting with smoking cessation. The American Pharmacists Association (APhA) "enthusiastically supports prioritizing tobacco cessation" as a goal to improve health in America.[6] Pharmacists in several states are able to prescribe nicotine replacement therapy or medications approved by the Food and Drug Administration (FDA) for tobacco cessation.[7] Maryland Senate Bill 440 (Pharmacists – Aids for the Cessation of Tobacco Product Use) was introduced in 2019 with the goal to permit prescribing and dispensing of tobacco cessation aids by pharmacists who met certain requirements. A modified version of this bill passed in the State Senate, but not the House.[8] However, with many nicotine replacement products being available over-the-counter without a prescription, pharmacists are able to recommend and educate on an appropriate product.

While the cardiovascular benefits of smoking cessation are well established, concerns for risk of increased blood pressure or exacerbating underlying coronary artery disease with the use of smoking cessation pharmacotherapy have been raised. Therefore, the safety of cessation products in patients with cardiovascular disease has been explored.[9–14] The purpose of this continuing education article is to provide an overview of the safety and efficacy of tobacco cessation products including bupropion sustained release (SR), nicotine replacement, and varenicline, and strategies to promote and support quitting smoking. Special attention will be paid to caveats for those with cardiovascular disease.

The 5 A's model (Ask, Advise, Assess, Assist, Arrange) is likely the most well-known brief intervention to promote smoking cessation. Despite the short period of time to employ this approach, a significant impact can be made. The steps of the 5 A's can be completed by one person in a practice setting or the components divided among staff.[4,15,16] The AAR (Ask-Advise-Refer) and the AAC (Ask-Advise-Connect) frameworks are also viable, evidence-based options.[4] It is important to ask about various forms of tobacco products, as not all tobacco users smoke and some use more than one form. Determining exposure to secondhand tobacco smoke is also of importance.[16] A wealth of resources are available to assist patients including print and electronic materials and quitlines. Recommended resources are included in Table 2.

Behavioral Intervention

While not the focus of this article, behavioral interventions play an integral role before, during, and after a patient quits smoking. The United States Surgeon General recently issued *Smoking Cessation: A Report of the Surgeon General* in 2020; the last report focused solely on this topic was published in 1990. In this report, Vice Admiral Jerome M. Adams, MD, MPH includes pharmacists as providers that can treat nicotine addiction and should inform and encourage those who smoke to quit. The report emphasizes that every patient interaction should be considered a "teachable moment" to motivate, assist, and sustain quitting.[4,15,16] Combining behavioral counseling and smoking cessation medications has been shown to improve abstinence compared to either strategy alone.[4,17,18] However, use of this dual strategy is low with only 4.7% of those who attempted to quit in 2015 implemented both of these tactics.[5]



ATRIUM Pocket Guide

Figure 1. Smoking Cessation

ATRIUM CARDIOLOGY COLLABORATIVE

First-Line Options	Instructions	Comments
Nicotine replacement therapy	See flip side	• Initiate patch plus a short-acting agent • See flip side for more details
Bupropion (Wellbutrin SR®)	150 mg daily x 3 days, then 150 mg BID	• Start 1–2 weeks before quit date • May use with one NRT product • Common adverse effects: agitation, dry mouth, headache, insomnia • Do not use in patients with an increased risk of seizures or history of anorexia/bulimia
Varenicline (Chantix®)	Days 1–3: 0.5 mg daily Days 4–7: 0.5 mg BID Days ≥8: 1 mg BID* *(Take with food and full glass of water)*	• Start 1–4 weeks before quit date • May consider NRT if monotherapy ineffective • Common adverse effects: insomnia, vivid dreams, headache, nausea (symptoms may improve with dose adjustments)

*Refer to product labeling for dose adjustments with renal dysfunction. Abbreviations: BID, twice daily; NRT, nicotine replacement therapy

Cognitive-behavioral therapy should also be used before, during, and after smoking cessation.

1-800-QUIT-NOW
www.smokefree.gov or www.lung.org/stop-smoking
Face-to-face counseling

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UNIVERSITY of MARYLAND SCHOOL OF PHARMACY

Pharmacotherapy Overview for those without Cardiovascular Disease

In patients without established cardiovascular disease, first-line pharmacological therapies for smoking cessation include bupropion SR, nicotine replacement, and varenicline. (Figures 1 and 2). PDF versions of these figures can be downloaded from:

https://blogs.pharmacy.umaryland.edu/atrium/2020/03/17/smoking-cessation-pocket-guide/

Second-line treatment options include clonidine and nortriptyline.[4,16] These agents are limited in use, likely due to their side effect profiles.

Varenicline is the preferred first-line therapy for patients who are able to afford therapy and without contraindications to use.[16,18–21] Combination nicotine replacement products (transdermal patch and one short acting product) should be considered as an alternative preferred therapy when varenicline cannot be used. These recommendations are based on the evidence that varenicline has been shown to be more effective than bupropion SR and nicotine replacement monotherapy in achieving and sustaining long-term abstinence.[22–24]

Combining varenicline and nicotine replacement may be considered in smokers who are unable to quit with either agent alone. This combination is typically well tolerated.[16,25] The combination of bupropion SR and varenicline does not appear to improve long-term abstinence compared to varenicline alone.[26]

Varenicline, a nicotinic receptor partial agonist, produces 50% of the maximal effect of nicotine on the nicotine receptor. Additionally, this agent binds to the nicotine receptor and decreases the pleasure from smoking. Varenicline use also has been shown to reduce withdrawal symptoms and nicotine cravings.[27] Nicotine withdrawal symptoms include, but are not limited to, irritability, sleep disturbance, weight gain, and anxiety. Stopping smoking one week after starting varenicline appears to be the most effective way to quit; however, a gradual reduction to stopping cigarettes by week 12 may be considered for some patients.[28] The dose of varenicline is gradually increased (Figure 1) to minimize the risk of gastrointestinal side effects, namely nausea. Treatment should be continued for at least 12 weeks, if tolerated, but can be used for an additional 12 weeks. A longer duration of use (i.e., 24 weeks) has been shown to improve long-term abstinence rates.[27,29]

ATRIUM Pocket Guide

Figure 2. Smoking Cessation

ATRIUM CARDIOLOGY COLLABORATIVE

NRT	Dose	Instructions	Adverse Effects
Patch	> 10 cigarettes/day: 21 mg/day x 6 weeks, then 14 mg/day x 2 weeks, then 7 mg/day x 2 weeks ≤ 10 cigarettes/day: 14 mg/day x 6 weeks, then 7 mg/day x 2 weeks	Apply/replace patch every 24 hours.	Vivid dreams, insomnia (remove prior to bedtime if these effects occur); skin irritation
Gum*†	First cigarette ≤ 30 minutes of waking: 4 mg First cigarette > 30 minutes of waking: 2 mg *Chew once per hour as needed (≥ 9 pieces/day for first 6 weeks; max 24 pieces/day)*	Chew until mouth tingles, then "park" inside cheek; repeat once tingle fades. Discard after 30 minutes.	Hiccups, heartburn, jaw soreness, mouth irritation, nausea
Lozenge*†	First cigarette ≤ 30 minutes of waking: 4 mg First cigarette > 30 minutes of waking: 2 mg *Use once every 1-2 hours as needed (≥ 9 lozenges/day for first 6 weeks; max 20 lozenges/day)*	Place between gum and cheek, and allow to dissolve. Do not chew.	Hiccups, heartburn, mouth irritation, nausea
Inhaler	Puff into mouth/throat until cravings stop. Use every 1-2 hours as needed. *Use at least 6 cartridges/day for first 3–6 weeks (max 16 cartridges/day)*	Inhale into back of mouth/throat (NOT into lungs) or puff in short breaths.	Mouth/throat irritation
Spray	1 spray in each nostril every 1-2 hours. *Use at least 8 doses per day (max 80 sprays per day)*	Do not sniff, swallow, or inhale through nose during administration.	Nasal irritation

*No food or drink 15 min before use and during use. †When combined with patch, use 2 mg dose unless patient is highly nicotine dependent. Abbreviation: NRT, nicotine replacement therapy

Created by Brent N. Reed, Pharm D, BCCP and Kristin Watson, Pharm D, BCCP with input from Storm E. Gaie, Pharm D, BCCP

Bupropion SR has been shown to minimize the pleasure from smoking and decrease nicotine withdrawal symptoms. Evidence supports that bupropion decreases gratification from smoking through inhibition of dopamine reuptake and/or inhibiting nicotine-induced release of dopamine.[30] Bupropion in combination with a nicotine f product that should be used for smoking cessation as this product has been the most studied for this indication. The patient should be started on bupropion SR 150 mg once daily for three days, then frequency should be increased to twice daily. This titration is to limit the risk of side effects (e.g., agitation, insomnia) of therapy.[31] There is evidence, albeit limited, that bupropion sustained released 150 mg once daily is as effective as twice daily.[32] This lower dose may be considered when a patient cannot tolerate 300 mg/day. Failure to use the correct formulation for smoking cessation can increase the risk of side effects. This is because the immediate release formulation is dosed three times a day, and adverse effects with this agent (e.g., seizure risk) appears to occur at peak concentrations.[33] There is limited data to support the efficacy of once daily bupropion (bupropion XL) for smoking cessation; however, it is likely to be as effective as the twice daily SR formulation, owing to its bioequivalence when comparable doses are used.[34,35]

Nicotine replacement therapy (not inclusive of e-cigarette use) reduces withdrawal symptoms but does not provide the enjoyable sensation from smoking. Patients have a higher chance of quitting if two nicotine replacement products are used (i.e., transdermal patch and a short acting form) compared to monotherapy. Short-acting replacement products (e.g., gum, lozenge) assist with controlling symptoms quickly and use on a scheduled basis to decrease the occurrence of cravings should be considered. Generally, it is suggested that short-acting products be used every hour. In addition, patients tend to be more adherent to the patch and allows discrete administration.[4] Combining a long-acting product (i.e., transdermal nicotine replacement) with a short-acting product should be encouraged in those who opt for nicotine replacement, owing to a higher rate of efficacy. Combination nicotine replacement therapy enables a constant delivery of nicotine with the transdermal product to mitigate withdrawal risk, and the short-acting formulation provides a prompt strategy to reduce withdrawal symptoms.[4,16] Dosing information and practical considerations for assisting a patient in choosing among nicotine replacement products are provided in Figure 2. Treatment is typically continued until the patient feels that they can be smoke-free without the use of nicotine replacement.

Bupropion SR, nicotine replacement therapy, and varenicline do not increase the risk of neuropsychiatric side effects, compared to placebo.[22] Varenicline and -bupropion SR (when used for smoking cessation) once carried a boxed warning pertaining to the risk of serious mental health side effects. This boxed warning was removed in 2016 based on results of a clinical trial required by the FDA.[22,36] Similar to all antidepressants, bupropion carries a boxed warning for suicidal ideation.[31,34] These first-line therapies, unless contraindicated, should be discussed with the patient as smoking cessation option. The efficacy and safety between regimens should be clearly outlined to enable the patient to make an informed decision. Ultimately, patient preference (e.g., class of medication, combination/one nicotine replacement product(s)), tolerability, efficacy, experience with prior smoking cessation aids, cost, comorbid conditions (e.g., seizure history, bulimia, dentition), and potential side effects are among factors to consider when developing a smoking cessation treatment plan.

E-cigarettes should not be considered as a means to treat nicotine addiction or suggested to patients as a replacement for other forms of tobacco. All forms of nicotine cause harm. Abuse of e-cigarettes is possible and may be greater than that of tobacco. The sensorimotor aspect of e-cigarettes may also promote long-term use and current data does not support e-cigarettes as a device to improve smoking cessation rates.[37–41]

Tobacco Cessation and Cardiovascular Disease

Secondhand smoke, low levels of cigarette use, and cigar use significantly impact an individual's risk of cardiovascular disease.[42,43] There appears to be a dose-response relationship between the number of cigarettes smoked and the risk of cardiovascular disease, with more cigarettes smoked per day leading to higher risk.[44,45] It appears that women who smoke are at higher risk of coronary heart disease than men.[46] Smoking increases a patient's risk of coronary heart disease, peripheral artery disease, abdominal aortic aneurysm, heart failure, ischemic stroke, and subarachnoid hemorrhage.[1,47] Fortunately, there are substantial benefits when a patient quits smoking:

People who stopped smoking more than 10 years ago are at the same risk of stroke as those who never smoked.[1]

The earlier in life a patient stops smoking, the better. Those who quit smoking between the ages of 25 and 34 gain an additional 10 years of life, whereas those who stop between the age of 55 and 64 gain 4 additional years.[44]

Smoking cessation reduces the risk of death and the need for amputation in those with symptomatic peripheral arterial disease.[48]

The risk of a recurrent non-fatal or fatal myocardial infarction is reduced up to 50 percent in patients who quit smoking.[49,50]

Pharmacotherapy for Smoking Cessation in those with Cardiovascular Disease

Patients who smoke and have cardiovascular disease should be informed about the benefits of quitting and providers should assess the patient's level of understanding of these concepts. Education should include a discussion on avoidance of secondhand smoke.[16] Also, any barriers to smoking cessation should be identified. Often, a patient may be misinformed or misunderstand the benefits of quitting and/or the risk of continued use. Concerns have been raised over the years of potential negative impacts of each smoking cessation aid in those with established cardiovascular disease. Nicotine replacement therapy produces sympathomimetic effects which can lead to vasoconstriction and coronary spasm. [11,51] Importantly, nicotine levels produced by replacement products are typically lower than what occurs with smoking.[16] There is conflicting evidence if nicotine replacement significantly increases the risk of arrhythmias, palpitations, and bradycardia.[10,52] However, studies have revealed that nicotine replacement does not increase the risk of death, stroke or cardiac events in those with cardiovascular disease.[11,52–54] Therefore, there is no need to wait to initiate nicotine replacement therapy for patients post-myocardial infarction.[53] It is generally accepted that nicotine replacement therapy is safer than continued smoking and can be considered as a treatment option in this patient population. However, nicotine replacement therapy should not be recommended in those who actively smoke owing to additive nicotine levels and increased risk of side effects.

Bupropion is a sympathomimetic analog and can elevate blood pressure and heart rate. Bupropion has also been shown to be safe in post-myocardial infarction patients.[9] In one study, there was no statistical difference in smoking cessation rates at 4 weeks and at the end of the 12-month study period between those who received bupropion SR or placebo when treatment was initiated prior to discharge for an acute myocardial infraction. Patients in this study were instructed not to smoke upon discharge. Bupropion SR is typically initiated before a patient stops smoking; however, that would not be appropriate in this setting. The results may have proven different if nicotine replacement therapy was permitted. Insomnia and dry mouth were the most common adverse events reports and the rate of side effects was between the two groups. The use of bupropion SR, nicotine replacement, varenicline, and placebo were evaluated in a randomized controlled trial to compare the cardiac risk of each of these agents.[10] A small portion of patients in this trial had known cardio- or cerebrovascular disease. There was no difference in incidence of major cardiovascular events and time to such events between groups. The rate of cardiovascular death, nonfatal stroke, or nonfatal myocardial infarction was low in this study with 96 weeks of follow-up. Continuous smoking cessation rates from weeks 9 to 12 were highest with varenicline (33.5%) compared to bupropion SR (22.6%), nicotine replacement therapy (23.4%), and placebo (12.5%) in the overall study. Those with a recent coronary or cerebrovascular event within the prior two months were excluded. Therefore, this data can be extrapolated to those with stable cardiovascular disease versus those with an acute event. There was no difference in changes in heart rate, blood pressure, and weight between the pharmacological treatment groups. The lack data demonstrating bupropion SR efficacy in the post-acute coronary syndrome patient population suggests that this agent should not be first-line therapy in those with an acute or recent cardiac event; however, its use appears to be safe.

An initial study with varenicline in those with cardiovascular disease raised concerns over its safety in this population. Although not statistically significant, there was an increase in the risk of nonfatal myocardial infarction, peripheral vascular disease, and the need for revascularization in one early clinical trial.[55] Results from a systematic review and meta-analysis also revealed an increased risk of serious adverse effects with varenicline. This prompted the FDA to notify the public that varenicline *"may be associated with a small, increased risk of certain cardiovascular adverse events in patients who have cardiovascular disease"*. This information was added to the *Warnings* and *Precautions* section of the product labeling.[56] Subsequent and more robust data demonstrated that varenicline is safe and effective in patients with stable cardiovascular disease and those hospitalized for an acute coronary syndrome.[10,12,57–60] Stable heart disease has been defined different ways. One definition is 12 months from an acute coronary event.[61] Another is "coronary artery disease more than 1 year after revascularization or in those with angiographically confirmed coronary artery disease not requiring revascularization".[62]

Expert Consensus from the American College of Cardiology

In 2018, the American College of Cardiology published a decision pathway on tobacco cessation developed by clinical experts. Recommendations for those with cardiovascular disease were included. The following are notable points from this publication.[16]

"Opt-out" version of the 5 A's[16]

The 5 A's is acknowledged; however, the authors note that an "opt out" approach may be considered. This strategy entails not asking if a patient is ready to quit, but offering smoking cessation treatment to all patients who smoke. The patient can then decide to accept or reject the recommendation. This strategy has been proven helpful to the lead author of this continuing education piece. The steps recommended in this pathway are:

1) ***Ask*** about all forms of tobacco use (e.g., cigarettes, e-cigarettes, dip and cigars) and secondhand smoke at each visit. Document the patient's response. A good question to start with is *"Do*

you ever use any tobacco products?". Those who do not use any form of tobacco can be asked *"In the past 7 days, were you exposed to secondhand smoke where you live?"*.

2) ***Assess*** the degree of addiction for those who smoke, risk for relapse for those who smoked previously, and exposure to secondhand smoke for those who do not smoke. The Heaviness of Smoking Index[63] is a validated and reliable tool to assess dependence and is as follows:

How many cigarettes do you use each day?
0 points: 10 or less
1 point: 11-20
2 points: 21-30
3 points: 31 or more

How soon after waking up do you smoke your first cigarette of the day?
0 points: after 60 minutes
1 point: 31 – 60 minutes
2 points: 6 – 30 minutes
3 points: within 5 minutes

Total score

0 – 2 points: low nicotine dependence
3 – 4 points: moderate nicotine dependence
5 – 6 points: high nicotine dependence

3) ***Advise*** each patient who uses tobacco to quit, and avoidance of secondhand smoke for non-smokers, unless they are resistant to hearing it. Educate patients on the benefits of cessation (not the harm with continued use).

4) ***Offer and Connect*** those who smoke with pharmacological treatment and behavioral support options. Treatment should be offered at each visit.

Motivational interviewing techniques should be employed in those who are not ready to quit. Encourage patients to adopt a smoke-free home and car policy.

5) ***Follow-up*** with patients to determine smoking status and provide treatment options when needed. This follow-up can occur at subsequent visits or over the phone, ideally within 2 to 4 weeks for those who made the decision to quit and start treatment. Follow-up for those who declined treatment should be assessed at each follow-up visit.

Regardless of the strategy taken to determine smoking status, providing education and recommendation, patients should be assessed for current tobacco use, risk for relapse, and exposure to secondhand smoke during each interaction with a healthcare professional.

Recommendations for which smoking cessation product(s) to consider for a patient with cardiovascular disease should be based on the setting in which therapy is initiated (inpatient versus outpatient) and the stability of the patient's cardiovascular disease.. Refer to Table 3 for a treatment algorithm. Pharmacists can play a role in the transition of care when patients are being discharged from the hospital to home, especially with reinforcement of patient education when patients are starting smoking cessation therapy.

Former Smokers[16]

Clinicians should determine risk of relapse for former smokers based on time elapsed since the patient last smoked. Those at highest risk of relapse are patients who quit smoking less than one month ago. Patients who have not smoked in the last month to six months are at moderately high risk of relapse. Treatment should be started or intensified if there are symptoms of nicotine withdrawal. Connections to psychosocial and/or behavioral treatment should occur. For the high and moderately high-risk groups, smoking status should be determined at each follow-up visit. It is suggested that follow-up occur every month and the patient is referred for treatment if they relapse. Patients who have not smoked for six or more months should be questioned about tobacco use at each follow-up visit and treatment should be offered when requested. It is imperative that exposure to secondhand smoke be determined and patients advised to have a smoke-free policy in their car and home.

Post-cessation Weight Gain[16,64]

The risk of weight gain may hinder a patient's readiness to quit. It has been reported that the majority of patients gain 3 to 6 kg in the first six months after quitting. Patients should be encouraged not to replace smoking with eating. For example, the patient can be instructed to take a walk, climb stairs, or engage in another form of physical activity when there is a desire to smoke. Exercise recommendations should be realistic based on the patient's current functional status and limitations. Smoking cessation should be the focus and should take priority over weight loss when a patient plans to stop smoking. Consider telling the patient to focus on maintaining their current weight.[18]

Smokeless Tobacco[16,65–68]

Oral snuff (ground tobacco placed between lips and gums) or chewing tobacco contain carcinogens and

other toxins. Patients may refer to smokeless tobacco as "dip" or "snus". It is unclear if use of smokeless tobacco increases the risk of cardiovascular disease in those without established disease. Use of this form of tobacco can lead to tooth decay and oral cancer, and an association with pancreatic and esophageal cancers have been reported. Patients should be counseled to stop, especially if cardiovascular disease is present. Varenicline coupled with behavioral support appears to be the most effective for this group of tobacco users. Nicotine lozenges may also be beneficial.

Conclusion

Smoking cessation is associated with substantial and favorable outcomes in patients with or without cardiovascular disease. In conjunction with cognitive-behavioral therapy, patients with stable cardiovascular disease are candidates for varenicline, nicotine replacement therapy, and bupropion SR. Varenicline and combination nicotine replacement therapy (patch plus one short-acting formulation) are the most effective. For patients with recent acute coronary syndrome, there is not a clear role for bupropion SR, owing to lack of evidence to demonstrate efficacy. E-cigarettes also should not be recommended. Patients and providers should engage in a dialogue about the best treatment option based on the patient's preference, prior quit attempts, access to treatment, cost, side effect profile, and comorbid conditions. Pharmacists are in a position to discuss smoking cessation with patient, engage in a conversation about treatment options, and provide encouragement and education. ●

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Active Learning

JW is a 62-year-old Caucasian man who wants to quit smoking. Until six months ago, he had smoked about 30 cigarettes a day for 15 years. He now smokes approximately one pack per day but is struggling to eliminate smoking fully. You ask JW what, if any, smoking cessation strategies he has tried in the past. He said that he had not considered any as he has heard from his friend that some smoking cessation medications can cause psychiatric side effects. He also said that he has been worried that smoking cessation medications would cause another heart attack.

PMH:

Myocardial infarction (12 months ago)
Chronic heart failure (left ventricular ejection fraction < 35%)
Hypertension
Hyperlipidemia
Depression – in remission x 6 months

Current Medications:

Atorvastatin 80 mg daily
Metoprolol succinate 200 mg daily
Spironolactone 25 mg daily
Lisinopril 40 mg daily
Aspirin 81 mg daily
Sertraline 100 mg daily

1. Which of the following correctly address JW's concern regarding the use of sustained release (SR) bupropion and varenicline in patients with cardiac conditions?
   a. Varenicline increases the risk of recurrent cardiovascular events in the post-acute coronary syndrome population.
   b. Bupropion SR increases the risk of death in patients with structural heart disease, including those with heart failure with a reduced ejection fraction.
   c. Varenicline and bupropion SR do not increase the risk of cardiovascular events in the post-myocardial infarction patients.
   d. Bupropion SR and varenicline increase the risk of stroke in patients with structural heart disease.

Answer C Both bupropion SR and varenicline appear to be safe in patients with a history of myocardial infarction based on the results of several trials. There does not appear to be an increased risk difference in incidence of major cardio- or cerebrovascular events, death, or recurrent cardiovascular events in patients with known cardiovascular disease with either bupropion SR or varenicline (C correct, A incorrect). Additionally, neither agent increase the risk of cardio- or cerebrovascular events or death in those with structural heart disease, including those with a reduced left ventricular ejection fraction or coronary artery disease (B and D incorrect)

2. Which of the following is/are would be considered safe for JW?
   a. Bupropion sustained release
   b. Combination nicotine replacement therapy (transdermal patch and one short-acting formulation)
   c. Varenicline
   d. All the above

Answer D. Bupropion SR, all nicotine replacement products, and varenicline have been shown to be safe in patients with stable or acute coronary disease (D correct, A, B, or C incorrect).

3. Which following statement is true in terms of neuropsychiatric side effects between bupropion SR, nicotine replacement therapy, and varenicline in those with stable psychiatric disorders or those without a psychiatric condition?
   a. These agents do not increase the risk of neuropsychiatric side effects compared to placebo in those with or without psychiatric disorders.
   b. Varenicline should not be used in those with unknown psychiatric disease as it carries a boxed warning for causing serious mental health side effects.
   c. Bupropion SR substantially increases the risk of suicidal ideation in patients with or without psychiatric conditions compared nicotine replacement therapy and varenicline.
   d. Nicotine replacement therapy is associated with a lower risk of worsening underlying psychiatric disorders compared to bupropion sustained released and varenicline.

Answer A. Based on the EAGLES (Evaluating Adverse Events in a Global Smoking Cessation Study, Lancet. 2016 Jun 18;387(10037):2507-20),) trial which was mandated by FDA, use of varenicline or bupropion SR was not associated with a difference in neuropsychiatric adverse events relative to nicotine patch or placebo. Patients with stable psychiatric conditions and those without known mental disorders were included in the EAGLES study (A correct, D incorrect). Boxed warning about possible psychiatric side effects for varenicline and bupropion 12- hour

SR were removed in 2016 based on the results of the EAGLES trial (B incorrect). The risk of suicidal ideation was not increased in the bupropion group in this trial. Bupropion carries a boxed warning for suicidality similar to other antidepressants (C incorrect).

4. JW decides to try varenicline. Which of the following are the most common side effects of this medication?
   a. Sedation, anxiety, and abdominal pain
   b. Nausea, headache, and abnormal dreams***
   c. Constipation, elevated blood pressure, and hot flash
   d. Nasal congestion, rash, diarrhea

Answer B. Compared to placebo, the common adverse reactions of varenicline include nausea, abnormal (e.g., vivid, unusual, or strange) dreams, constipation, flatulence, and vomiting (B correct, A, C, and D incorrect).

5. Alternative scenario: JW had a myocardial infarction one month ago instead of 12 months. He was discharged from hospital two weeks ago, and has not further chest pain. Everything else in the case is the same with the exception of him being on ticagrelor too. He asks if he can use transdermal nicotine patches to assist quitting. Which of the following is correct regarding transdermal nicotine replacement in patients with a recent myocardial infarction? JW:
   a. cannot use this product as use is contraindicated within 3 months of a myocardial infarction; he can try a short-acting nicotine replacement product.
   b. cannot use any nicotine replacement products within the 3 months after his myocardial infarction.
   c. can consider use alone; combination with a short-acting nicotine replacement product.
   d. should wait at least 12 months before trying any form of nicotine replacement therapy.

Answer C. Nicotine replacement therapy does not increase the risk of death, stroke or cardiovascular disease in those with cardiovascular disease and nicotine replacement therapy is most effective when combined with a short-acting agent (C correct). Any form of nicotine replacement therapy is considered safe to start in patients with coronary disease, even within the index admission for an acute coronary syndrome (A, B, and D incorrect).

Table 1. Benefits of Quitting Smoking Over Time[4]	
Time after quitting	**Benefits**
20 minutes	Heart rate drops
12 hours	Carbon monoxide level returns to normal
2 weeks - 3 months	Myocardial infarction risk begins to lower. Lung function begins to improve
1-9 months	Coughing and shortness of breath decrease
1 year	Risk of coronary heart disease is half that of a smoker's
2-5 years	Stroke risk is reduced to that of a nonsmoker's. Risk of mouth, throat, esophagus, and bladder cancers is halved within 5 years
10 years	Lung cancer death rate is about half that of a smoker's. Risk of kidney and pancreas cancer decreases
15 years	Risk of coronary heart disease is similar to a nonsmoker's

Table 2. Smoking Cessation Resources	
Pharmacists	
Websites	• American Pharmacists Association: https://www.pharmacist.com/tobaccocessation • Agency for Healthcare Research and Quality: www.ahrq.gov/prevention/guidelines/tobacco/index.html • Million Hearts® millionhearts.hhs.gov/tools-protocols/tools/tobacco-use.html
Treatment Recommendations	• 2018 ACC Expert Consensus Decision Pathway on Tobacco Cessation Treatment: A Report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. Available at: https://www.onlinejacc.org/content/accj/72/25/3332.full.pdf • Initiating Pharmacologic Treatment in Tobacco-Dependent Adults. An Official American Thoracic Society Clinical Practice Guideline Available at: https://www.onlinejacc.org/content/accj/72/25/3332.full.pdf • Office of the Surgeon General. U.S. Department of Health and Human Services. Public Health Service. Smoking Cessation. A Report of the Surgeon General: Executive Summary. Rockville, MD. 2020. Available at: https://www.hhs.gov/sites/default/files/2020-cessation-sgr-executive-summary.pdf
Patients	
Websites	• www.Smokefree.gov • www.CDC.gov/quit • www.heart.org/en/healthy-living/healthy-lifestyle/quit-smoking-tobacco
Quitlines	• 1-800-QUIT-NOW (English) • 1-855-DÉJELO-YA (Spanish) • 1-800-838-8917 (Cantonese and Mandarin) • 1-800-556-5564 (Korean) • 1-800-778-8440 (Vietnamese)

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Editorial

Patient Knowledge and Attitudes Regarding Pharmacy Access to Hormonal Contraceptives

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Introduction

Unintended pregnancy has significant social, economic and health consequences.[1,2] Nearly half of all pregnancies in the United States (US) are unintended, a rate much higher than in other developed countries.[3] Certain populations are disproportionately affected, with women of color, those who are low-income, aged 18–24, or cohabiting having the highest rates of unintended pregnancy.[3]

Barriers to contraceptive use, such as lack of access, encourage nonuse and gaps in use, which contributes to the high prevalence of unintended pregnancy in the US.[4] Reducing these barriers by making contraceptives available without a prescription has been proposed. Historically, except for barrier methods and emergency contraception, most contraceptive methods have been available via prescription only. A large body of literature indicates that over-the-counter (OTC) access to oral contraceptive pills is safe and effective.[5] Efforts to reclassify oral contraceptives as OTC have support from leading medical groups, including the American Medical Association (AMA), American College of Obstetricians and Gynecologists (ACOG), and American Academy of Family Physicians (AAFP).[6,7,8]

Currently, OTC hormonal contraceptives are not available in the US and the topic remains a widely debated policy issue. In the meantime, individual states have enacted legislation or regulations allowing pharmacists to prescribe and dispense self-administered hormonal contraceptives in an effort to expand access. As of December 2020, Maryland is among the 12 states which allow women to obtain a hormonal contraception prescription directly from a pharmacist without a collaborative practice agreement.[9] While the current laws do not reclassify hormonal contraception as OTC, they do allow women who would otherwise be restricted by work hours, childcare, transportation and financial considerations more options to access contraception.

As this legislation was recently enacted, it is not clear if women in Maryland are aware of this option. Research describing women's attitudes toward accessing oral contraception through a pharmacist is lacking. This report examines women's familiarity with contraceptive access options and their attitudes towards pharmacy access to hormonal contraception at one primary care center.

Methods

This cross-sectional, survey-based study was conducted at the University of Maryland Family Medicine Practice, an urban outpatient primary care center. The University of Maryland Institutional Review Board reviewed this study. Using a convenience sample, adult women of reproductive age (18-50 years) were recruited to participate in the investigator-developed survey during their family medicine office visit from February to April 2020. Surveys were administered in private rooms. Individuals who were ambivalent to becoming pregnant or actively desired pregnancy, as well as those with known history of infertility, were excluded.

In addition to demographic data and desire to become pregnant, participants responded to three Likert-

style questions related to ease of obtaining hormonal contraception, opinion on pharmacy access to hormonal contraception, and likelihood of utilizing this service. Participants were also asked to indicate current contraception method and barriers they have experienced to accessing contraception. Descriptive statistics including means and percentages, were used. Relationships between categorical variables were examined using Fisher's exact test.

Results

Seventy women completed the survey, with a response rate of 82%. Sixteen surveys were excluded based on ambivalence to or desire for pregnancy and 54 women were included in the final analysis. The majority of participants were Black (n=54, 100%), aged 26-35 years (n=24, 44%), and single (n=36, 67%) [Table 1]. Eighty percent (n=43) were currently using contraception, with over one-third using long-acting reversible contraception (LARC, e.g. intrauterine device, n=19, 35%) and one-third using barrier methods (e.g. condoms, n=18, 33%).

Participants were provided a list of 7 potential barriers to accessing hormonal contraception, an option to enter additional free-text barriers, and an option to select 'nothing, it was very easy'. Seventeen participants (31%) selected 'nothing, it was very easy', 5 participants (9%) omitted this question, and 2 participants (4%) entered free text indicating they had not attempted to access hormonal contraception. The remaining 30 women (56%) reported 34 barriers reported, most often related to inconvenience of office visits, including difficulty scheduling an appointment (n=17, 50%) and limited office hours (n=7, 20%) [Figure 1]. Despite this, most participants ranked obtaining hormonal contraception as very easy (n=18, 35%) or somewhat easy (n=16, 31%).

Patient awareness of pharmacy access to hormonal contraception is low. When asked "Are you aware that you can obtain oral birth control directly from a pharmacist without needing a prescription from your primary care doctor?" 80% of participants answered "No". Participants of all age groups surveyed reported overwhelmingly in favor of pharmacy access to hormonal contraception for themselves [Figure 2]. Survey respondents also felt that this service would be beneficial for other women. Specifically, 85% of women said they were either somewhat (n=21, 39%) or strongly (n=25, 46%) in favor of pharmacy access to hormonal contraceptives, and 85% said they were either somewhat (n=19, 35%) or very (n=27, 50%) likely to personally utilize pharmacy access to hormonal contraceptives. Data trended toward increased favorability among younger participants (aged 18-25 years) and women currently using oral contraceptive pills, though this did not reach statistical significance.

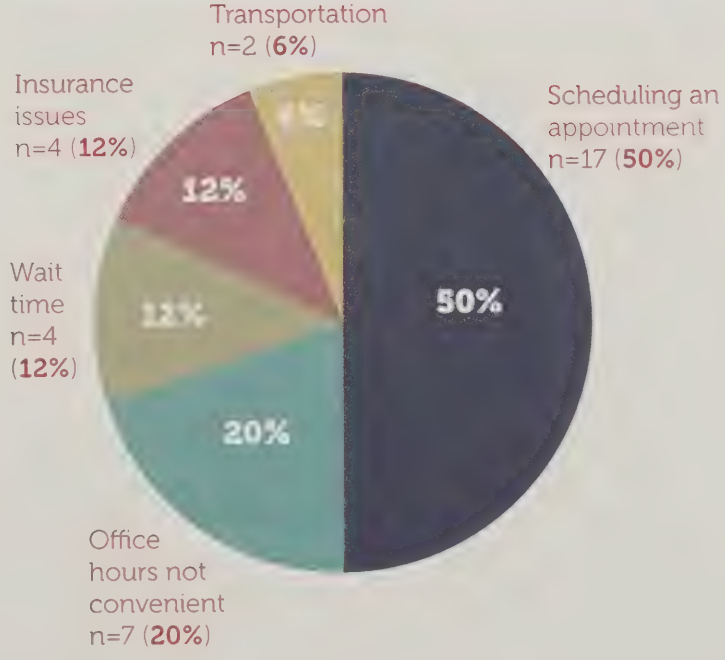
Participants were asked to leave free responses on why they were or were not likely to utilize pharmacy access to hormonal contraception. Some responses in favor of pharmacy access included: "doctors can be hard to see," "long wait time at doctor's office," "no doctor appointment needed" and "self-control". Responses from women not likely to utilize pharmacy access to hormonal contraception included: "closer relationship with your doctor," "want to discuss health issues with doctor," and "already have long-acting contraception because taking oral contraceptive pills (OCP) is not convenient."

Discussion

Our data show a low level of awareness (20%), but high level of acceptance (85%), of pharmacy access to hormonal contraceptives among surveyed women of reproductive age desiring pregnancy prevention at one primary care center in Maryland. Less than one in four women surveyed were aware that pharmacists could prescribe and dispense self-administered contraception without a physician's prescription. One possible explanation is that the new option was only recently introduced, and therefore knowledge of such has not had time to be disseminated throughout the community. Also, there was unlikely a focus in the primary care office to guide women with established medical care towards seeking contraception through pharmacy access. These surveys were conducted just over one year after this legislation went into effect in the state of Maryland. These data suggest opportunities exist to educate women who may benefit from the availability of this service.

Once educated on the legislation and availability of pharmacy access to hormonal contraception, women surveyed were overwhelmingly supportive of increased access to contraception through pharmacy prescribing and dispensing. All demographics support pharmacist contraceptive prescribing significantly more than not. In terms of whether they are likely to personally utilize

Figure 1. Reported Barriers to Obtaining Oral Contraceptive Pills (N=34)



the pharmacy access option, women most commonly indicated convenience as a favorable factor for them. At the same time, some responses highlighted women's perceived trust in their primary care provider. While not statistically significant, there was a trend toward respondents indicating lower likelihood to utilize pharmacy access for hormonal contraceptives with increasing age (e.g. ages 36-50 years), which may be interesting to explore in future studies. Women may develop more comorbid chronic medical conditions or more established relationships with their current providers as they age, which could influence their decisions on where to receive health care. While the availability of pharmacy access to hormonal contraception largely targets women without established primary care or reproductive health providers, it is interesting that one-third of women surveyed in this study, all of whom were accessed at their primary care center after a provider visit, endorsed interest in utilizing this service.

One-third of surveyed women who have ever tried to obtain hormonal contraceptives reported access barriers, similar to previously reported literature.[4] In a previous study, lack of insurance was cited as one of the biggest barrier to access.[4,10] It is interesting that despite all the women in this study having access to insurance and established primary care at the time of the survey, a similar percentage reported barriers. It is possible that a portion of these women reflected on their prior experiences accessing contraception while not having insurance, as the survey question did not set limits on time or circumstance when barriers were encountered. Another possible explanation is that health insurance status in prior studies may reflect the socioeconomic status of the individual. While the Affordable Care Act helps reduce direct financial barriers and is an important step towards improving contraceptive access and affordability, indirect costs and burdens associated with visiting a provider to obtain a prescription must still be considered. Such considerations include time lost from work or school, childcare costs, transportation to/from the health care provider, and the limited hours for care. The need for a prescription has been reported as a barrier in past studies, noting increased and perhaps unnecessary direct and indirect costs of the office visit for the purpose of obtaining contraception.[10,11] Similarly, women in this study reported significant barriers associated with office visits in the context of their past attempts to obtain a prescription for contraception, including difficulty scheduling, inconvenient office hours, and long wait times. Such barriers might be amplified in younger, less financially robust patient groups, and might be a motivating factor for their indicated favorability to utilize direct from pharmacy access to hormonal contraceptives. Extended availability and walk-in appointments at many community pharmacies may help address these barriers.

Conversely, women who reported they were less likely to utilize this service cited a close relationship with their primary care provider and the desire to discuss their other conditions as major contributing factors. The option of pharmacist prescribing and dispensing self-administered contraception is not intended to supplant patient-provider relationships. Given the multimodal health care needs of women of reproductive age, pharmacists participating in this service should facilitate linkages to primary care or reproductive health providers for women who do not already have identified providers. Another theme identified by women not intending to use this service was the current use of LARCs, which must be inserted in a healthcare office. As these are highly effective contraceptive methods, pharmacists should refer women who are interested in this option to providers with expertise in this area.

Limitations

This study has a relatively small size, and thus the results may not be generalizable. Participants were also recruited after encounters within a provider office, therefore women struggling to access the healthcare system and those who are uninsured would not be included. These populations may be more likely to benefit from pharmacy access to hormonal contraception. Despite these limitations, this study provides insights into and attitudes toward pharmacy access to hormonal contraception in women of childbearing age currently using a variety of contraception methods.

Conclusions

Women's enthusiasm for this service suggests that pharmacies can play an important role in reducing barriers to contraception access. Increased advertisement of the availability of these services is needed to improve awareness in women who may be interested in, or may benefit from, accessing contraception through pharmacies. The findings of this survey highlight the importance of continued advocacy for easy access to safe and effective methods to prevent unintended pregnancies.

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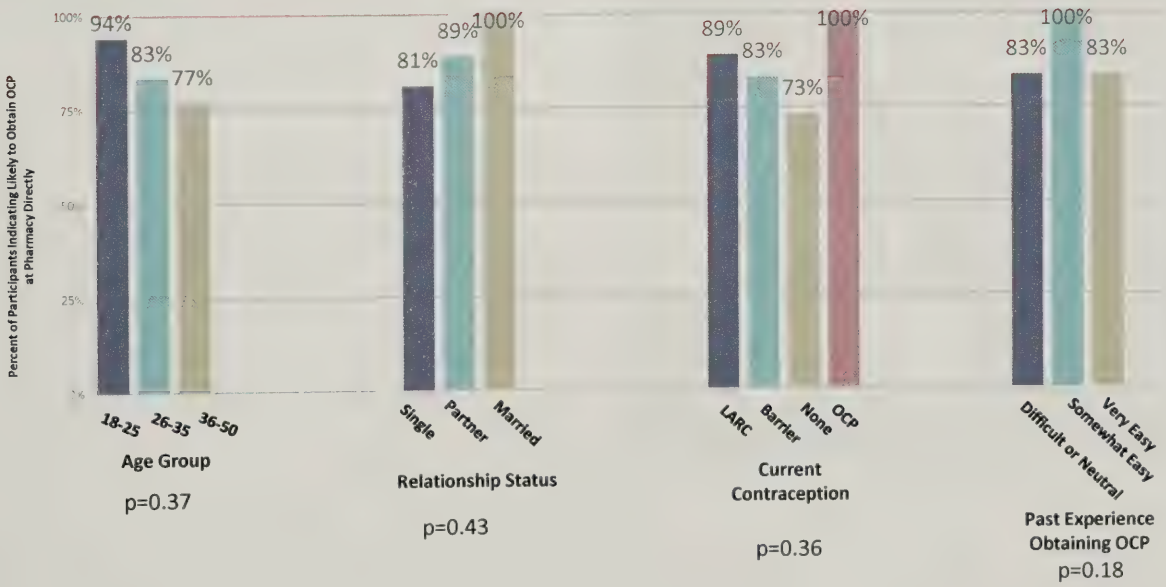
Table 1. Demographics and Contraceptive History

Characteristic	Total (N=54)
Age, n (%)	
18-25	17 (31.5%)
26-35	24 (44.4%)
36-50	13 (24.1%)
Relationship Status, n (%)	
Single	36 (66.7%)
Long-term Partner	9 (16.7%)
Married	8 (14.8%)
Separated	1 (1.9%)
Current Contraception Method, n (%)	
LARC	19 (35.2%)
Barrier	18 (33.3%)
None	11 (20.4%)
OCP	6 (11.1%)
Past Experience Obtaining OCP, n (%)	
Very Difficult	4 (7.4%)
Somewhat Difficult	4 (7.4%)
Neutral	10 (18.5%)
Somewhat Easy	16 (29.6%)
Very Easy	18 (33.3%)
Never Tried To Get OCP	2 (3.7%)
LARC, long-acting removable contraception; OCP, oral contraceptive pills	

Figure 2. Favorability of Pharmacy=Access of Hormonal Contraception



2021 Maryland Pharmacy Coalition Legislative Day

On February 2, more than 200 student and professional pharmacists participated in the 21st Annual Maryland Pharmacy Coalition (MPC) Legislative Day! In past years the community covered the Capitol with white coats – for 2021 it was a "Zoomed" event. The virtual event facilitated the opportunity for new activities including an education session on the legislative process; a panel discussion with pharmacy advocates; and letter-writing/Twitter campaign. Special thank you to Stacy Dalpoas, Ray Love, Monet Stanford, Brian Hose and Richard De-Benedetto who shared how they got involved in advocacy and why it is important for everyone to use their voice to impact the profession.

Participants requested support for legislation that will improve several key areas of public health by utilizing pharmacist accessibility and knowledge to:

1. increase medication and treatment adherence for chronic conditions, particularly those with substance use disorders and mental illness; and

2. increase immunization rates and disease prevention.

MPC priorities for the 2021 legislative session are:

HB135/SB84 Pharmacists – Administration of Self-Administered Medications and Maintenance Injectable Medications

Sponsored by: Delegate K. Lewis Young and Senators R. Young and J. Waldstreicher

The bill expands pharmacy scope of practice to allow pharmacist-administration of injectable maintenance medications. Allowing pharmacists to administer maintenance injectable medications will increase treatment access to populations especially those with mental health illness and opioid dependence. After several years of negotiation the legislation is supported by MedChi, Maryland Nurses Association, Maryland Nurse Midwives Association, Maryland Psychiatric Society and NAMI Maryland, among others. It was recently amended to be treated as emergency legislation. It was passed unanimously by the House of Delegates in 2020.

HB TBD/SB TBD Health Occupations – Pharmacists – Administration of Vaccinations

Sponsored by: Delegate A. Kelly and Senator M. Augustine

The bill modifies age-requirements for expanded access to pharmacy-based immunizations. It authorizes a pharmacist, who meets certain requirements, to administer CDC-recommended vaccinations to an individual that is at least three years-old but under the age of 18 without a prescription. This legislation requires parental/guardian consent. Forty-two other states already allow pharmacists to provide vaccinations without prescriptions to adolescents, including 11 states that do not have an age-threshold for pharmacist-administered immunizations. The bill reflects what is already in practice under emergency order at the federal and state level.

Many legislators and participants shared photos on social media – take a look by following #MDPharmacyCares on social media!

Editorial

Esketamine Clinic at the University of Maryland Medical Center, Mid-Town Campus

By: Megan J. Ehret, PharmD, MS, BCPP, Recipient of the 2020 MPhA Foundation and Upshur-Smith Laboratories Excellence in Innovation Award

Major depressive disorder (MDD) affects approximately 17.3 million American adults, or about 7.1% of the US population age 18 and older, in a given year. Depression is the cause of over two-thirds of the 30,000 reported suicides in the US each year. In 2018, there were 652 deaths by suicide in Maryland, with an age-adjusted rate of 10.2 per 100,000 population. This is 3% higher than 2017. While there are many current treatments for MDD, many of them take significant time to achieve therapeutic benefits.

Working with the faculty from the University of Maryland, School of Medicine, Department of Psychiatry and the University of Maryland Medical Center, Mid-Town Campus Pharmacy, an interprofessional esketamine clinic is being developed for patients with treatment resistant depression or in adults with MDD with suicidal thoughts or actions. Esketamine is a novel intranasal antidepressant that has proven to be efficacious in treatment resistant depression and MDD with suicidal thoughts or actions in conjunction with an oral antidepressant. Due to the risks of serious adverse outcomes resulting from sedation, dissociation, and abuse and misuse, esketamine is only available through a restricted program (Spravato, REMS). Esketamine must be administered under the direct supervision of a health care provider with patients being monitored for adverse effects for at least 2 hours following administration.

Developing the certified treatment center for esketamine required focused attention to the numerous details that are required for use of the medication. With the interprofessional team, I led the efforts in developing policies and procedures for the utilization of the medication. A formulary review and medication use guide were developed within the University of Maryland Medical Center Pharmacy and Therapeutics Committee. Currently, the infrastructure, billing, and EPIC build are occurring. With the world wide pandemic, the establishment of our clinic has been delayed. As the psychiatric pharmacist in the clinic, I will assisting in the continued development of the clinic policies and procedures, establishing the role of the pharmacists in the clinic, and screening and monitoring of patients. When the clinic opens, the pharmacist team will be involved in screening patients, verifying insurance coverage, monitoring patients, and handling of the medication inventory. I will also be involved in the training of additional pharmacy staff to assist in the clinic.

The target audience for the treatment center will be those patients diagnosed with treatment resistant depression or MDD with suicidal thoughts or actions. Our clinic will be able to provide a much needed service to the members of our community in Baltimore who are suffering with depression. Additionally, our clinic will allow for patients with various insurance options to be treated with their own internal providers still continuing as part of their care. Additionally, our clinic will offer pharmacy consultation services if needed to assist with medication regimens and monitoring of patients.

Thank You to the MPhA Foundation Donors!

Contributions to the MPhA Foundation are greatly appreciated. The generosity of donors supports our mission to invest in the future of pharmacy by supporting student pharmacists; recognizing practice innovation and advancements; and enhancing philanthropy that supports leadership.

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COVER STORY

Rising to the Challenge

MPhA's 139th Annual Convention—where pharmacists, pharmacy technicians, and student pharmacists from the surrounding regions convene, learn, network and engage with colleagues and peers!

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Maryland Pharmacists Association, 9115 Guilford Road, Suite 200, Columbia, MD 21046, call 443.583.8000, or email aliyah.horton@mdpha.com.

President's Pad

Maryland pharmacists, pharmacy technicians, and student pharmacists have been showcasing our professional capabilities and caring for our patients across the state through the COVID-19 vaccine roll-out and administration. I have enjoyed hearing members share their success stories both in-person and through social media, such as professors being vaccinated by their students and community pharmacists partnering with schools of pharmacy to support larger public health initiatives. I am so proud of the work each of you is doing to reinforce the importance of pharmacists and members of the integrated healthcare team to the public. On a personal note, I have never seen patients so excited to get vaccinated—what a nice change!

As we look forward, there are still many unknowns that we will be navigating throughout 2021, and I encourage each of you to continue rising to the challenge.

The inspiring work being done across the state and nation has coincided with several successes during the recent state legislative session as well. Through the advocacy work of MPhA and many of you, HB-135 will authorize pharmacists to administer maintenance injectable medication that treat a chronic disease, condition, or disorder. It includes medication for the treatment of a psychiatric disorder or substance use disorder, contraception, and vitamins. Additionally, HB-601 put into practice the positive outcome of the Rutledge vs. PCMA Supreme Court case by repealing the exclusion of plans subject to ERISA from state regulation related to payment. Congratulations to those of you who contributed to the advocacy and influencing of state leaders to support the needs of pharmacists and our patients.

As we look forward, there are still many unknowns that we will be navigating throughout 2021, and I encourage each of you to continue rising to the challenge. One way to stay connected is to participate in the MPhA Annual Convention, which will be held virtually on June 5-6th, 2021. The virtual component will be hosted via Whova using the Zoom platform, and on Sunday we will host in-person and physically distanced events in several locations across the state. I hope you will consider attending and look forward to interacting with many of our members! If you have not yet registered, please visit https://www.marylandpharmacist.org to do so.

Kerry Cormier

Kerry Cormier, PharmD
MPhA President 2020-2021

MPhA Welcomes OUR NEWEST MEMBERS

MARYLAND PHARMACISTS ASSOCIATION

Welcome to MPhA: If you meet these new members, please welcome them to the MPhA Pharmily and be sure to invite them to join a committee or attend a networking event!

Engaged

Dale Morton – Rockville
Jami Butz – Lutherville
Jessica Boh – Lexington Park
Michael Findley – Baltimore

Informed

Abdul Moeez – Princess Anne
Aml Farag
Amanda Loomis – Hamden
Anne Rizzo – Nottingham
Brittany Edwards – Towson
Budne Reinke – Silver Spring
Carrie Assar – Annapolis
Ellen Nastase – Mechanicsville
Erica Mcall – Bel Air
Flavia Rasetto – Bethesda
Funmi Oja – Randallstown
Garima Avasthi – Looknow India
Henoke Shibeshi
Ina Sirkis – Baltimore
Jaeyeon Kim – Columbia
Jiali He – Gaithersburg
Jin Kyung Song – Philadelphia
Kevin Aikens – Olney
Kierra Dotson – Hanover
Kwabena Nimarko – Germantown
Kim Robbins – Harrington
Lucille Akanegbu – Ellicott City
MacKenzie Hrubey
Michelle Ly – Chino
Mohammad Semati – Philadelphia
Nick Frita
Ogechi Ogbonna – Pikesville
Salil Tiwara – Looknow India
Samichhya Pandel – Elkridge
Sherra Matthews
Sunjin Kim – Gaithersburg
Yvette Waples – Upper Marlboro

Pharmacy Technicians

Braillie Corbin – Cumberland
Heaven Thomas – Rawlings

Students

Abena Ankomah, Columbia – Shenandoah University
Aliyah Carter, Beltsville – UMB
Aminah Jones, Belcamp – UMB
Andrew Pikounis, Baltimore – UMB
Anthony Azubike, Laurel – UMB
Arit Ntekim, Bowie – UMB
Ashley Osores, Gaithersburg – VCU
Benson Sanga, Hyattsville – UMES
Bela Pandya, Pasadena – UMB
Breah Johnson, Baltimore – UMB
Brittany Gray, Baltimore – NDU
Brittany Wentzel, Pasadena – Shenandoah University
Caitlin Benkart, Montgomery Village – UMB
Catherine Kim, Baltimore – UMB
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Danielle Kalinousky, Baltimore – UMB
Derek Edwards, Baltimore – UMB
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Elise Lee, Baltimore – NDU
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Erica Aarto, Columbia – UMB
Francis Wright, Silver Spring – Marshall University
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Lauren DiFacol, Towson – NDU
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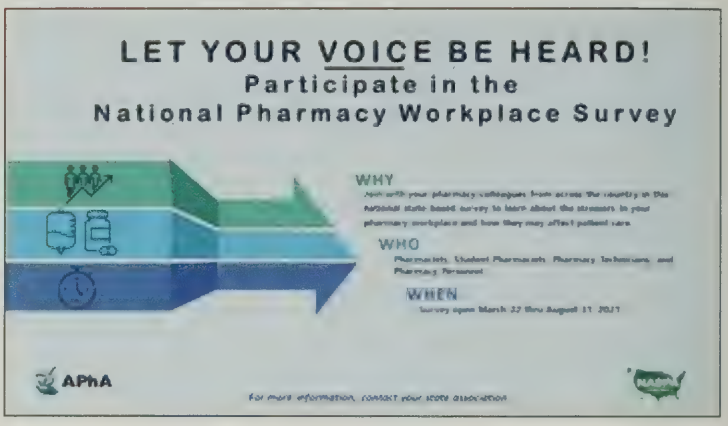
Yoonna Choi, Baltimore – UMB
Zachary Becouvarakis, Hampton – UMES

Make History—Participate in the National State-based Pharmacy Workplace Survey

We know that well-being continues to be a critical, complex issue for the profession and patient safety, but quantitative data on how pharmacy workplace issues may affect patient safety is lacking. And that is why MPhA is pleased to be a part of a national state-based pharmacy workplace survey project in collaboration with other state pharmacy associations, American Pharmacists Association (APhA), and the National Alliance of State Pharmacy Association (NASPA) to bring this opportunity to you!

We have heard pharmacists are reluctant to discuss workplace issues and possible solutions because their supervisors don't want to hear or welcome them. Even worse, the reluctance is also attributed to fear of retaliation from employers. This survey gives you the opportunity to voice those concerns. It is 100% anonymous. MPhA will not have access to your responses. Your individual survey response will be included in a nationwide database that will be held centrally and confidentially. We will only have access to aggregated data that we can use to tell your story in our advocacy and educational efforts.



Join with your pharmacy colleagues from across the country and make history by participating in the first of its kind national state-based pharmacy workplace survey. Just 10 minutes of your time is all that is needed to complete the survey which can be accessed by scanning the code above. The survey will be open until August 31st.

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The Bowl of Hygeia award program was originally developed by the A. H. Robins Company to recognize pharmacists across the nation for outstanding service to their communities. Selected through their respective professional pharmacy associations, each of these dedicated individuals has made uniquely personal contributions to a strong, healthy community. We offer our congratulations and thanks for their high example. The American Pharmacists Association Foundation, the National Alliance of State Pharmacy Associations and the state pharmacy associations have assumed responsibility for continuing this prestigious recognition program. All former recipients are encouraged to maintain their linkage to the Bowl of Hygeia by emailing current contact information to awards@naspa.us. The Bowl of Hygeia is on display in the APhA History Hall located in Washington, DC.

Mid-Year Meeting Recap

MPhA 2021 MID-YEAR MEETING February 21 • Virtual

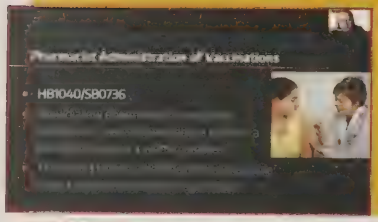
On behalf of the Maryland Pharmacists Association (MPhA), thank you to everyone who attended the 2021 Mid-Year Meeting, Sunday, February 21! Your presence made this event a great success!

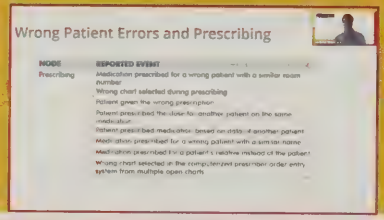
This was the first virtual Mid-Year Meeting and we utilized an event app called Whova, to increase opportunities for engagement. The app allowed attendees to participate in virtual meet-ups with other guests to connect and network, converse through various discussion topics in the community board, post pictures, and view live streams of the CE sessions. Feedback showed that attendees enjoyed the enhanced opportunities, and we will be using the app again for the Virtual 139th Annual Convention, June 5-6, 2021.

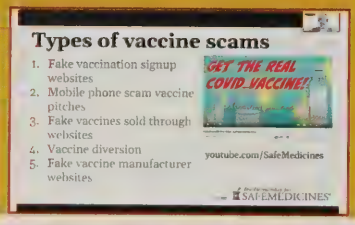
Session topics included:

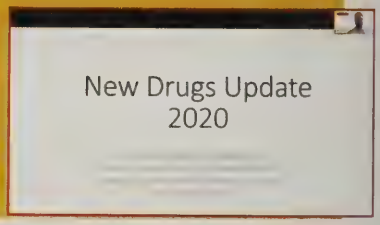
- Pharmacy Updates on COVID
- Mental Health Awareness in the Time of COVID-19
- Pediatric Vaccinations
- 5 Tips to Effectively Incorporate Diversity and Inclusion at your Workplace
- Current Medication Safety Challenges Facing Community Pharmacy
- Crime and Policy: Counterfeit Medicines
- New Drugs Update
- Maryland Legislative Update

Several of these sessions are available as online CE via our online learning platform.









Congratulations to the Whova App Top Leader Board Participants

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- Lauren Correia
- Surinder Singal
- Joseph DeMino
- Lynette Bradley-Baker
- Lauren Lakdawala
- Careen-Joan Franklin
- Frances Leach Greene


Deanna Tran


Amy Nathanson


Stella Kim


Cherokee Layson-Wolf

The House of Delegates approved the slate of nominees for the MPhA 2021- 2022 Board of Trustees Election.

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- Deanna Tran
- Marci Strauss

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- Erin South
- Seema Kazmi

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- Anne Lin

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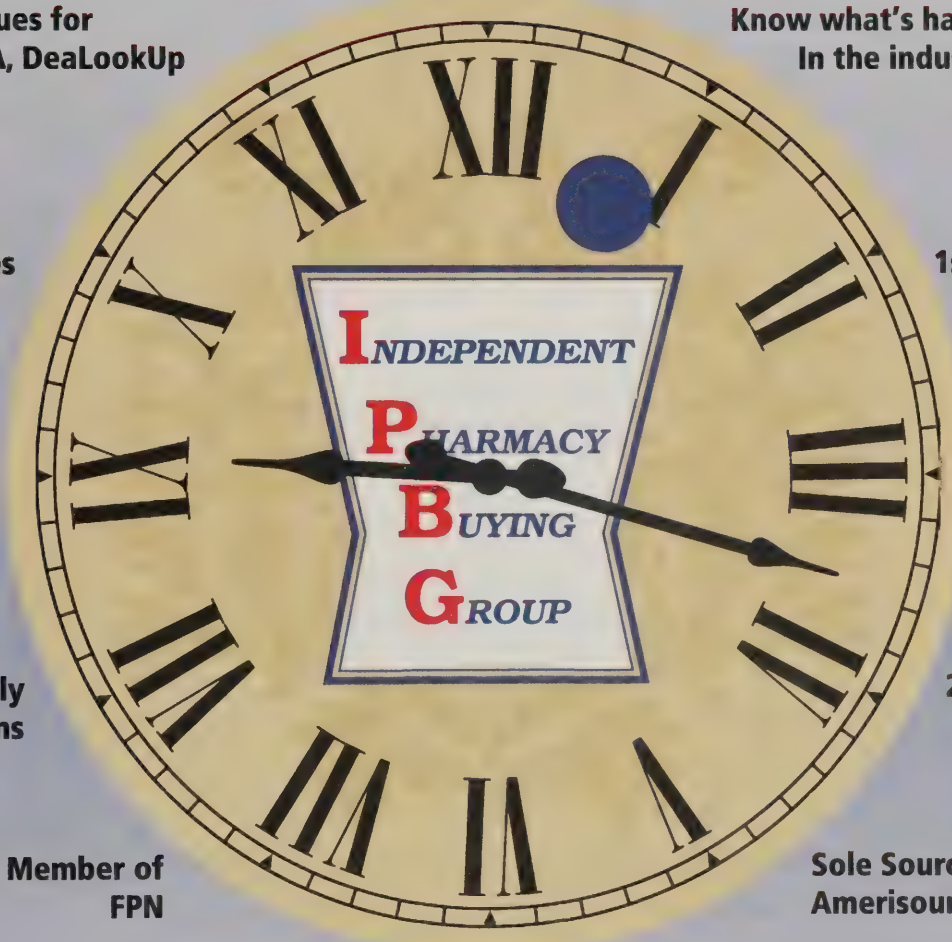

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You're invited to attend MPhA's 139th Annual Convention where pharmacists, pharmacy technicians, and student pharmacists from the surrounding regions convene, learn, network and engage with colleagues and peers! We hope you will come join us for a two-day virtual convention with ample opportunities to broaden your knowledge in the pharmacy profession.

Registration Rates

Early Bird Rates End May 28, 2021!
MPhA Members - $179
Non-members (Includes Free MPhA Informed member type) - $204
MPhA Student Pharmacists and Technician Members - $99
Non-member Student Pharmacists and Technicians - $124

After May 28, 2021 all rates increase by $25.

Highlights include:

- CEUs on the most current trends in the pharmacy profession
- Opportunities to network, connect, and re-connect with your peers
- Chances to gain new perspectives from our dynamic speakers
- Recognition of professional accomplishments
- In-person and virtual social activities all ages can enjoy

Continuing Ed

Dapagliflozin: More than an Andidiabetic

Ebony Isis Evans, Pharm D
Kathleen J. Pincus, PharmD, BCPS, BCACP

Learning Objectives

After this activity, the *pharmacist* will able to:

1. Describe the mechanisms of action of SGLT2 inhibitors.
2. List the important adverse drug effect counseling points for SGLT2 inhibitors.
3. Evaluate the results of the DAPA-CKD and DAPA-HF trials.
4. Discuss the role in therapy for dapagliflozin.

After this activity, the *pharmacy technician* will able to:

1. Describe the mechanisms of action of SGLT2 inhibitors.
2. List the important adverse drug effect counseling points for SGLT2 inhibitors.
3. Describe the key findings of the DAPA-CKD and DAPA-HF trials.

Keywords

Diabetes, Heart Failure, Chronic Kidney Disease

Thirty-seven million people in the United States (US), or 15% of US adults, have chronic kidney disease (CKD), and over 6 million people in the US have heart failure (HF). Heart disease accounts for approximately 30% of deaths in people with CKD, and 90% of deaths in people with heart failure. While there are established guidelines for improving outcomes for patients with these conditions, novel therapeutic approaches to reduce morbidity and mortality are still needed. Recently, evidence has emerged for the use of sodium glucose cotransport 2 (SGLT2) inhibitors in CKD and HF.

When managing CKD, the key therapeutic objectives are to prevent the progression of kidney function decline, treat reversible causes, and manage complications of kidney disease. Kidney Disease: Improving Global Outcomes (KDIGO) guidelines recommend the use of Angiotensin-Converting Enzyme (ACE) inhibitors or Angiotensin II Receptor Blockers (ARBs) in patients with CKD to prevent progression.[1] The KDIGO guidelines were last updated in 2012, before the completion of any of the SGLT2 inhibitor trials that will be discussed in this article, and thus do not currently mention the use of SGLT2 inhibitors for use in CKD.

For patients with heart failure with reduced ejection fraction (HFrEF), the goals of therapy are to reduce morbidity (e.g., reduce symptoms, improve health-related quality of life, and decrease the rate of hospitalization), and mortality. The most recent heart failure guidelines are the 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure Guidelines.[2] These guidelines recommend the use of an ACE inhibitor, ARB or angiotensin receptor–neprilysin inhibitor (ARNI), in conjunction with an evidence-based beta blocker (BB) and aldosterone antagonist for HFrEF patients to reduce mortality and morbidity. Diuretics are recommended for the relief of symptoms from volume overload; however, they do not provide any reduction in morbidity and mortality. Again, SGLT2 inhibitors are not yet included in these guidelines. This article will focus on the evidence of use of SGLT2 inhibitors, specifically dapagliflozin, to improve cardiovascular and renal outcomes in people with and without diabetes.

Introduction to SGLT2 Inhibitors —

Sodium glucose cotransporters (SGLT) are proteins responsible for maintaining glucose balance in the blood. One of the most prominent proteins in this family, the SGLT2 protein, is found in the proximal renal tubules and is responsible for the majority of the reabsorption of filtered glucose back into circulation. Inhibiting this protein prevents the reuptake of glucose by the kidneys from glomerular filtrate and thus lowers the glucose level in the blood and promotes excretion in the urine. As this protein cotransports both sodium and glucose, SGLT2 inhibitors also reduce sodium reabsorption and increase delivery to the distal tubule.

SGLT2 inhibitors were developed and initially approved for the management of type 2 diabetes mellitus (T2DM), and clinical trials have shown their ability to significantly reduce A1C compared to placebo.[3] These drugs have been shown to have many clinical benefits outside of solely reducing blood glucose levels. There are several clinical trials demonstrating that certain SGLT2 inhibitors reduce the risk of heart failure hospitalizations, major cardiovascular events, and the progression of CKD (Table 1). The Empagliflozin, Cardiovascular Outcomes, and Mortality in Type 2 Diabetes (EMPA-REG OUTCOME)[3] trial found a significantly lower percentage of participants with a major adverse cardiovascular event (MACE), as well as reduced CKD events with empagliflozin compared to placebo. The Canagliflozin and Renal Outcomes in Type 2 Diabetes and Nephropathy (CREDENCE)[4] trial found a significantly lower risk of renal death or progression to end-stage renal disease (ESRD) in participants who received canagliflozin compared to placebo. Additionally, the Canagliflozin and Cardiovascular and Renal Events in Type 2 Diabetes (CANVAS)[5] trial showed a lower risk of CV events, renal decline, and heart failure hospitalization, but a greater risk of amputation. These trials also showed a lower risk of hospitalization for heart failure for their respective treatment arms. However, these trials only showed benefits in HF and CKD in patients that also had T2DM, thus it was unclear whether these benefits extended to patients without T2DM. The mechanism by which these drugs confer benefit to patients with HFrEF or CKD is not clearly defined, but it is hypothesized to be due to the mechanism of diuresis. In HFrEF, it is hypothesized SGLT2 inhibitors induce osmotic diuresis resulting in greater electrolyte-free water clearance and thus greater fluid clearance from the interstitial fluid. This is a distinctly different mechanism than that of other diuretic classes that results in congestion relief with minimal impact on blood volume and organ perfusion. For CKD patients, SGLT2 inhibitors have been shown to reduce hyperfiltration and decrease inflammatory and fibrotic responses of proximal tubular cells, followed by a progressive recovery and stabilization of renal function.

Emerging Evidence —

Two of the most recent trials of SGLT2 inhibitors released in 2019 and 2020 focus on the HFrEF and CKD benefits of dapagliflozin in patients without diabetes. Dapagliflozin (Farxiga) is a SGLT2 inhibitor approved in the US in 2014 for use as an antidiabetic agent to treat patients with T2DM. Interestingly, despite dapagliflozin being an antidiabetic, these recent trials demonstrated consistent benefit outside of blood glucose lowering in patients both with and without T2DM.

Dapagliflozin in Patients With Heart Failure and Reduced Ejection Fraction (DAPA-HF) is a trial designed to determine whether the addition of dapagliflozin in patients with HFrEF, with or without diabetes, reduced the rates of cardiovascular death or worsening of heart failure.[6] The trial randomly assigned 5000 patients receiving standard medical care to receive either dapagliflozin 10 mg once daily or placebo. Standard medical care included an ACE inhibitor, an ARB, or sacubitril–valsartan plus a BB, unless contraindicated. In addition, the use of a mineralocorticoid receptor antagonist was encouraged. Patients with T2DM continued their antidiabetic therapies, but doses could be adjusted to minimize the risk of hypoglycemia. All of the participants enrolled in the trial had HFrEF New York Heart Association's (NYHA) functional class II-IV (NYHA II: 68%, NYHA III: 32%, and, NYHA IV: 1%). The mean age of participants was 66 years and 42% had T2DM. Patients with T1DM were excluded from this trial. In the treatment group, there was a statistically significant reduction in worsening of heart failure (16.3% vs. 21.2% (HR 0.74; 95% CI 0.65-0.85; P<0.001)), measured by the requirement of hospitalization or urgent visit resulting in intravenous therapy for heart failure, compared to placebo. There were very similar hazard ratios, and no statistically significant difference in benefit between patients with T2DM compared to those without. There was however a difference in hazard ratio for the primary outcome based on NYHA classification, with less treatment benefit in patients in NYHA class III or IV than in class II (class II: HR 0.63 (95% CI 0.52-0.75), NYHA class III or IV: HR 0.90 (95% CI 0.74-1.09)). There was still a clinical benefit seen in patients with NYHA class III or IV, however, investigators note a greater effect for SGLT2 inhibition may be present among those with NYHA class II HF symptoms. As secondary outcomes, DAPA-HF also found that dapagliflozin provided benefit in regards to cardiovascular death, worsening renal function, and all-cause mortality. Overall, the results of this trial showed that dapagliflozin provides a reduction in the risk of heart failure hospitalization in patients with HFrEF, whether they have T2DM or not. In 2020, The U.S. Food and Drug Administration (FDA) added the treatment of adults with HFrEF to reduce the risk of cardiovascular death and hospitalization for heart failure as an indication for dapagliflozin. It is the first in its class to be approved to treat adults with NYHA functional class II-IV HFrEF.

As previously mentioned, other trials have already shown the benefit of SGLT2 inhibitors in CKD, however, those trials only included patients with T2DM. Dapagliflozin in patients with chronic kidney disease (DAPA-CKD) is a trial that assessed whether dapagliflozin affects the progression of CKD in patients with or without T2DM.[7] This trial included patients (n=4,034) with an eGFR as low as 25 mL/min/1.73 m^2 and a urine albumin to creatinine ratio (ACR) between 200 and 5,000 mg/g. Sixty-eight percent of the participants in the treatment arm had T2DM. The mean eGFR of patients receiving dapagliflozin was 43 mL/min/1.73 m^2 (eGFR ≥60 11%, eGFR 45-60 30%, eGFR 30-45 46%, eGFR <30 14%). Participants were randomized to receive either dapagliflozin 10 mg once daily or placebo. There was a statistically significant reduction in the occurrence of the primary outcome (decline of ≥50% in eGFR, new ESRD, renal mortality, or cardiovascular mortality) in the treatment group. Secondary outcomes also showed a reduction in cardiovascular or all-cause mortality in the treatment group. The results showed that, in patients with CKD with or without T2DM, dapagliflozin was associated with less progression of CKD and renal mortality. The primary outcome was similar regardless of T2DM status and severity of eGFR reduction. This study was stopped early once the analysis found clear evidence of benefit of dapagliflozin, which may have led to an underpowering of the less common endpoints.

In both trials, the incidences of adverse effects and discontinuation were similar between treatment groups. In the DAPA-CKD trial, only the rates of fracture and volume depletion were higher with dapagliflozin; however, neither were statistically significant. In the DAPA-HF trial, only the incidence of diabetic ketoacidosis (DKA) was more prevalent in

the treatment group; however this was only a 0.1% difference and only occurred in patients with pre-existing diabetes.

Both trials also assessed whether dapagliflozin had any benefit on cardiovascular and all-cause mortality. Dapagliflozin produced risk reductions for both outcomes in each trial. However, cardiovascular mortality was only assessed as part of the composite outcome in each trial, and all-cause mortality was assessed as a secondary outcome in both trials. Additional research in patients with HFrEF is needed as the DAPA-HF trial mostly included patients with moderate heart failure and found a differential in benefit among patients of different NYHA symptom classes. It may also be useful to investigate the effect of dapagliflozin in patients with CKD on different baseline medications regimens. All patients in DAPA-CKD were on an ACE inhibitor or an ARB, so it is unclear whether dapagliflozin would have benefit in patients who are intolerant to those medications. Despite these limitations, these trials provide evidence that dapagliflozin has proven benefit outside of just lowering blood glucose levels in patients with diabetes.

Place in Therapy —

Despite the emerging clinical evidence, consensus has not been reached for the place in therapy of SGLT2 inhibitors, especially in patients without diabetes. Per the American Diabetes Association (ADA) 2021 guidelines, SGLT2 inhibitors are recommended as second line therapy for patients with diabetes who have certain comorbidities.[8] Despite these recommendations and proven clinical benefit, some providers are still hesitant to initiate these new therapies. Although the data for dapagliflozin is very compelling, it is very new, which may contribute to the hesitancy of some providers. Some providers are wary of their side effect profile, which includes hyperkalemia, genitourinary infections, bone fractures, DKA, and amputations. Even though trials have shown the incidence of these side effects are relatively low compared to placebo, the risk still exists. Genitourinary infections can be very troublesome to patients and are often a reason for nonadherence or self-discontinuance. It is also important to note that canagliflozin previously had a black box warning for the risk of amputations that has since been removed due to new safety evidence from clinical trials. In addition, several drugs in this class have an eGFR cutoff that limits the potential candidates for use, especially in the CKD and T2DM populations (able 2). Despite their many benefits, SGLT2 inhibitors are not the most effective antidiabetic agents in terms of A1C reduction, being bested by insulin, metformin, sulfonylureas, and GLP-1 agonists. As far as glycemic control goes, patients with T2DM and without compelling comorbidities are likely best managed with an alternate second line medication such as a GLP-1 agonist or insulin. The largest benefit of SGLT2 inhibitors, and what sets them apart from other antidiabetics, is the benefit they provide in risk reduction for CKD, HFrEF hospitalizations, and ASCVD. The KDIGO guidelines have not been updated since the release of this data; however ACC has released a 2021 update to their HFrEF guidelines to include SGLT2 inhibitors. The update recommends that after initiation of BB and angiotensin antagonist, addition of an aldosterone antagonist should be considered, and SGLT2 inhibitors should also be considered for NYHA class II-IV patients.

For patients with T2DM and CVD, HFrEF, and/or proteinuric CKD, SGLT2 inhibitors as a class are beneficial. Dapagliflozin, though, has demonstrated a specific place in therapy based on the aforementioned trials proving its benefit in risk reduction of CKD, HFrEF, and CVD in patients without T2DM. Additionally, it also has a labeled indication for use in HFrEF without T2DM and was recently granted breakthrough therapy designation in the US for patients with CKD, with and without T2DM. To date, similar trials supporting the use of other SGLT2 inhibitors in patients with T2DM have not been published. Three additional clinical trials with dapagliflozin are currently underway, including DELIVER and DETERMINE, testing dapagliflozin in patients with HFrEF and HFpEF respectively; and DAPA-MI testing dapagliflozin in patients without T2DM following an acute myocardial infarction or heart attack. As the data continues to evolve, the role of SGLT2 inhibitors, and dapagliflozin specifically, will likely continue to shift.

Conclusion —

Diabetes, HFrEF, CKD, and CVD are some of the most common causes of morbidity and death in Americans and are also common indications for a majority of pharmacologic therapies. These conditions often coexist and work antagonistically to worsen patient outcomes. Finding the most effective medications to manage patients who have several comorbidities while balancing the risk of side effects can be difficult but is paramount to optimizing patient care. SGLT2 inhibitors have demonstrated benefit in preventing progression of certain comorbidities in patients with T2DM. Recent data with dapagliflozin specifically provides evidence of cardiovascular and renal benefits to patients regardless of their diabetes diagnosis. This provides a new option for providers to consider for management of large populations of patients with multiple comorbidities.

These recent trials, DAPA-CKD and DAPA-HF, clearly show the benefit of dapagliflozin in patients with HFrEF or CKD, with or without diabetes, but also raise questions about the benefit of other SGLT2 inhibitors. Further trials will be necessary to confirm whether this is a class benefit, or specific to dapagliflozin alone.

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Active Learning Patient Case

WM is a 71-year-old AA male who presents to your outpatient clinic as a new patient. He was referred to you by one of the resident physicians for management of his medications and ASCVD risk reduction.

His PMH includes HTN, dyslipidemia, and HFrEF. The patient has a prior history of an MI. He is a current smoker and is not ready to quit.

His most recent labs show: A1C 6.2%, BP 124/78 mmHg, eGFR 62 mL/min/1.73 m^2, LDL 191mg/dl, HDL 47mg/dL, TC 269 mg/dL, TG = 153mg/dL BMI 27 kg/m^2

His current medication list: lisinopril 40mg daily, metoprolol succinate 200mg daily, simvastatin 20mg daily, aspirin 81mg daily, multivitamin daily

1. Would patient WM be a good candidate for the addition of an SGLT2 inhibitor?
   a. No, because the patient does not have diabetes
   b. Yes, because he has CKD
   c. No, because he is overweight, and this medication causes weight gain
   d. Yes, because he has comorbid HFrEF
2. Which medication on WM's medication list is not an ideal therapy because the patient is indicated for a more intensive treatment?
   a. Metoprolol succinate 200mg once daily
   b. Lisinopril 40mg daily
   c. Aspirin 81mg
   d. Simvastatin 20mg daily
3. If you were to start the patient on an SGLT2 inhibitor today, based on their labeled indications, which would be the best choice?
   a. Canagliflozin
   b. Dapagliflozin
   c. Empagliflozin
   d. Ertugliflozin
4. Which of the following outcomes have SGLT2 inhibitors demonstrated in clinical trials?
   a. Reduced risk of developing heart failure
   b. Reduced severity of heart failure with preserved ejection fraction
   c. Reduced risk of hospitalizations from heart failure with reduced ejection fraction
   d. Reduced risk of progression from pre-diabetes to type 2 diabetes
5. WM has seen commercials about dapagliflozin side effects and is curious to know what side effects he's most likely to encounter.
   a. Weight gain
   b. GI disturbances
   c. UTIs
   d. Shortness of breath

Explained Answers (Patient Case)

1. Answer D
   a. SGLT2 inhibitors have proven benefit in reducing the risk of hospitalizations for patients with HFrEF (D is correct)
   b. Dapagliflozin, an SGLT2 inhibitor, has proven benefit for HFrEF in patients without diabetes (A is incorrect). Although beneficial in patients with CKD, this patient does not have CKD based on their eGFR or PMH (B is incorrect). SGLT2 inhibitors are likely to cause weight loss (C is incorrect).
2. Answer D
   a. The patient is indicated for a high intensity statin but is currently only on a moderate intensity statin (D is correct)
   b. The patient's BP is well controlled on this therapy and these two medications are at their maximum doses (A and B are incorrect). The patient would not benefit from an increased dose of aspirin if using it for secondary prevention (C is incorrect)
3. Answer B
   a. Dapagliflozin is the only SGLT2 inhibitor with a labeled indication for HFrEF in patients without diabetes (B is correct)
   b. Canagliflozin, Empagliflozin, nor Ertugliflozin have labeled indications for patients without diabetes (A, C, and D, are incorrect)
4. Answer C
   a. DAPA-HF showed that dapagliflozin reduced the risk of HFrEF related hospitalizations (C is correct).
   b. Clinical trials have not shown any reduction in the risk of developing HF (A is incorrect). None of the clinical trials have looked at patients with HFpEF (B is incorrect). These medications have not been shown to prevent progression from pre-diabetes to T2DM (D is incorrect).
5. Answer C
   a. Genitourinary infections are the most common adverse effects caused by SGLT2 inhibitors (C is correct)
   b. SGLT2 inhibitors are not known to cause GI disturbances or shortness of breath (B and D are incorrect). SGLT2 inhibitors are more likely to cause weight loss (A is incorrect)

Table 1

Trial	Intervention	Primary Outcome	Secondary outcome	Conclusion
Empagliflozin, Cardiovascular Outcomes, and Mortality in Type 2 Diabetes (EMPA-REG) — 2015	Empagliflozin 10mg Empagliflozin 25mg Placebo	**CV mortality, nonfatal MI, or nonfatal stroke:** 10.5% vs. 12.1% (HR 0.86; 95% CI 0.74-0.99; superiority P=0.04, noninferiority P<0.001)	**HF hospitalization:** 2.7% vs. 4.1% (HR 0.65; 95% CI 0.50-0.85; P=0.002) **HF hospitalization or CV mortality excluding fatal stroke:** 5.7% vs. 8.5% (HR 0.66; 95% CI 0.55-0.79; P<0.001)	Reduced rate of CV events and slowed the progression of CKD disease in patients with T2DM and high CV risk.
Canagliflozin and renal outcomes in diabetic nephropathy (CREDENCE) — 2019	Canagliflozin 100mg Placebo	**ESKD, doubling of baseline serum creatinine, renal mortality, or cardiovascular mortality:** Canagliflozin 100 mg/d 43.2 events/1000 P-Y vs. placebo 61.2/1000 events/1000 P-Y (HR 0.70, 95% CI 0.59-0.82; P=0.00001)	**CV death or hospitalization for heart failure:** 31.5 vs. 45.4/1000 P-Y (HR 0.69; 95% CI 0.57–0.83; P<0.001) **CV death, MI or stroke:** 38.7 vs. 48.7/1000 P-Y (HR 0.80; 95% CI 0.67–0.95; P=0.01), NNT=40 (23-165) **HF hospitalization:** 15.7 vs. 25.3/1000 P-Y (HR 0.61; 95% CI 0.47–0.80; P<0.001)	In patients with T2DM and diabetic nephropathy, canagliflozin reduces the risk of the composite end-point of end-stage kidney disease, doubling of serum creatinine from baseline, and death from renal or CV disease.
Canagliflozin and cardiovascular and renal events in type 2 diabetes (CANVAS) — 2017	Canagliflozin 200mg Canagliflozin 100mg Placebo	**CV mortality, nonfatal MI, or nonfatal stroke:** 26.9 vs. 31.5 participants with an event per 1000 patient-years (HR 0.86; 95% CI, 0.75 to 0.97; P<0.001 for noninferiority; P=0.02 for superiority)	**CV mortality:** 11.6 vs. 12.8 participants with an event per 1000 patient-years (HR 0.87; 95% CI 0.72 to 1.06; NS) **40% reduction in eGFR, renal-replacement therapy or renal death:** 5.5 vs. 9.0 participants with event per 1000 patient-years (HR 0.60; 95% CI, 0.47 to 0.77) **Hospitalization for heart failure:** 5.5 vs. 8.7 participants with event per 1000 patient-years (HR 0.67; 95% CI, 0.52 to 0.87)	In patients with T2DM at high risk for CV events, canagliflozin had a lower risk of CV events and reduced the rate of renal decline and heart failure hospitalization, but a greater risk of amputation.
Dapagliflozin in Patients With Heart Failure and Reduced Ejection Fraction (DAPA-HF) — 2019	Dapagliflozin 5mg Dapagliflozin 10mg Placebo	**Worsening heart failure (hospitalization or urgent visit resulting in IV therapy for HF) or CV mortality:** 16.3% vs. 21.2% (HR 0.74; 95% CI 0.65-0.85; P<0.001)	**Cardiovascular death or heart-failure hospitalization:** 16.1% vs 20.9% (HR 0.75; 95% CI 0.65-0.85; P<0.001)	Among individuals with HFrEF (NYHA II-IV) with or without T2DM, dapagliflozin decreased rates of CV death, worsening HF, and all-cause mortality.
Dapagliflozin in patients with chronic kidney disease (DAPA-CKD) — 2020	Dapagliflozin 10mg Placebo	**Decline of ≥50% in eGFR, new ESRD, renal mortality, or CVD mortality:** 9.2% vs. 14.5% (HR 0.61; 95% CI 0.51-0.72; P<0.001; NNT=19)	**Decline of ≥50% in eGFR, new ESRD, renal mortality:** 6.6% vs. 11.3% (HR 0.56; 95% CI 0.45-0.68; P<0.001)	In patients with CKD, with and without T2DM, dapagliflozin was associated with less progression of CKD, renal mortality, or CVD mortality, when compared to placebo.

Table 2

Drug	Renal adjustments
Empagliflozin (Jardiance)	- Do not to initiate when eGFR is <45 mL/min/1.73m^2. Should not be used for glycemic control if eGFR is persistently <45, but renal and cardiac benefits have been shown in patients with an eGFR below this threshold - eGFR ≥45: No dosage adjustment necessary - eGFR <30: Manufacturer's label states use is contraindicated; however, in patients previously established on empagliflozin, some experts continue use off label at a dose of 10 mg daily for diabetic kidney disease
Canagliflozin (Invokana)	- eGFR ≥60: No dosage adjustment necessary - eGFR 30 to 60: Maximum of 100 mg once daily - eGFR <30 mL/minute/1.73 m^2 with: o Urinary albumin excretion >300 mg/day: Initiation is not recommended; however, patients previously established on canagliflozin may continue 100 mg once daily o Urinary albumin excretion ≤300 mg/day: Initiation not recommended in patients without severely increased albuminuria
Dapagliflozin (Farxiga)	- eGFR ≥45: No dosage adjustment necessary - eGFR 30 to <45: o Hyperglycemia: Manufacturer does not recommend use o Heart failure: No dosage adjustment necessary o Diabetic kidney disease (off-label): No dosage adjustment necessary - eGFR <30: o Hyperglycemia: Use is contraindicated o Heart failure: Insufficient data to support a dosage recommendation o Diabetic kidney disease (off-label): No dosage adjustment necessary for eGFR ≥25. Should not be initiated in an eGFR <25 to 30

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This issue's quiz on **Dapagliflozin: More Than an Antidiabetic** can be found online by scanning the code below or go to https://www.lecturepanda.com/a/Dapagliflozin:

(1) Enter your name and contact information.

(2) Take the quiz and click "Complete Quiz."

2021 Legislative Session Update

Key pharmacy legislative victories were achieved in the 2021 Legislative Session related to pharmacy scope of practice and PBM reform.

HB 135 – Pharmacists – Administration of Self–Administered Medications and Maintenance Injectable Medications (Christopher King Access to Treatment Act)

Primary Sponsor: Delegate Karen Lewis Young
Effective Date: Upon Enactment

The bill authorizes pharmacists to administer maintenance injectable medications that treat a chronic, disease, condition or disorder. It includes medication for the treatment of a psychiatric disorder or substance use disorder, contraception and vitamins. It may not be a biological product.

- The product must be prescribed by an authorized prescriber; in accordance with a standing order issued by an authorized public health official; or under protocol.
- Regulations establishing standard procedures must be developed by September 1, 2021 by the State Boards of Physicians, Nursing and Pharmacy. The procedures include training requirements, communications to prescribers, patient financial notifications and protocols after the medication is administered.
- The education requirement is waived if the pharmacist receives the training as part of their PharmD.
- The bill requires payment parity by regulated by the state for patient assessments and administration of the medications.

HB 601 – Pharmacy Benefit Managers – Revisions

Primary Sponsor: Delegate Nicholaus R. Kipke
Effective Date: January 1st, 2022

This bill will put into practice the positive outcome of the Rutledge vs. PCMA Supreme Court case, by repealing the exclusion of plans subject to ERISA from state regulation.

- Carriers may not enter into agreements with pharmacy benefit managers (PBMs) that have not registered with the Insurance Commissioner.
- Specifically focuses on PBMS that provide pharmacy benefit services on behalf of carriers. As defined by the bill "carriers"are the state employee and retiree health and welfare benefits program, an insurer, a non-profit health service plan or a health maintenance organization that: provides prescription drug coverage or benefits in the state; and enters into an agreement with a PBM for the provision of pharmacy benefit management services.
- Contract forms or amendments to contracts must be submitted to the Insurance Commissioner at least 30 days before it becomes effective. The Commissioner may review and disapprove the submittals.
- Requires the Maryland Insurance Administration to report to the General Assembly on the scope of the Rutledge vs. PCMA case and the application of this bill by December 31, 2021.

HB 1040 – Health Occupations – Pharmacists – Administration of Children's Vaccines – Study and Temporary Authority

Primary Sponsor: Delegate Ariana B. Kelly
Effective Date: July 1, 2021

This bill allows licensed pharmacists from July 1, 2021 to June 30th, 2023, to administer FDA-approved, CDC-recommended immunizations to children between the ages of 3 to 17 years old, provided several requirements are met. These requirements are in line with the current emergency order and current MD statute and regulations. If the emergency order expires prior to January 1, 2022, the authority in this legislation will end on April 30, 2022.

The bill requires a report by the the Maryland Department of Health and Board of Pharmacy to be given to the General Assembly by December 1, 2021. It will provide information on what they determine to be important for setting policies authorizing pharmacists to administer vaccines to children. The report will include:

- number of vaccines administered to children under the act
- Effectiveness and efficiency of ImmuNet
- Whether the authority has impacted changes in well-child visits with pediatricians

If the authority continues beyond January 1, 2022, the same entities are required to produce a more extensive report by December 1, 2022.

SB 298 – State Board of Pharmacy – Pharmacy Closure – Notice to Customers (The Dennis Robin Act)

Primary Sponsor: Senator Edward R. Reilly
Effective Date: October 1st, 2021

This bill establishes additional requirements that an owner of a pharmacy must complete in anticipation of their pharmacy being closed for more than 7 consecutive days. At least 30 days before the anticipated closing of the pharmacy, the owner must do the following:

- post a notice of the closing date in the pharmacy itself that is easily seen and understood by its customers.
- If the pharmacy has a website, a notice must be placed there.
- In addition, a written AND verbal notice of the closing must also be given to each customer who picks up either a prescription or a refill.
- It is also acceptable for pharmacy owners to mail a notice to every pharmacy customer who has current and authorized refills of any prescription on file at said pharmacy, but this must be completed at least 14 days before the anticipated closing date.

Any notice given to customers must contain the following pieces of information:

- The date that the pharmacy is expected to close (if it is known).
- The name of the pharmacy to which the closing pharmacy will be transferring all customers' records and prescriptions.
- That if a customer wants their prescriptions and records sent to a different pharmacy than the one mentioned above, the customer may request this.

This bill also requires that the Maryland Board of Pharmacy make regulations that define what "closing of a pharmacy" means, as well as provide exceptions to the requirements stated above.

SB 537 Pharmacists – Require Notification and Authorized Substitution – Lower Cost Drug or Device Product

Primary Sponsor: Senator Stephen S. Hershey, Jr.
Effective Date: October 1, 2021

- Requires pharmacist to inform patient of a therapeutically equivalent brand name drug that is the lowest-cost alternative to the originally prescribed generically equivalent and of its cost difference.
- If the patient is using prescription drug coverage the determination for the cost differential is based on the patient's prescription drug benefits and formulary, IF it is readily available.
- Authorizes pharmacists to substitute a therapeutically equivalent brand name drug or device product to the originally prescribed generically equivalent drug or device. Similar to what is already done for brand to generic.
- The pharmacist must maintain a record that the indicates the patient was notified in writing or orally of the options.

HB 14 – Pharmacists Prescription Drug Device Labels – Expiration Dates

Primary Sponsor: Delegate Ken Kerr
Effective Date: Upon enactment

- Modifies labeling requirements for drugs or devices dispensed in the manufacturers original packaging
- An expiration date of the drugs shall be:
  - o The expiration date set by the manufacturer; or
  - o A shorter period as determined by the pharmacist

HB 28 – Public Health – Implicit Bias Training and the Office of Minority Health and Health Disparities

Primary Sponsor: Delegate Joseline Pena-Melnyk
Effective Date: October 1, 2021

- Requires applicants for the renewal of a license or certificate issued by a health occupations board to complete an approved implicit bias training program the first time they renew their license or certificate after April 1, 2022.

SB 3 Preserve Telehealth Access Act of 2021

Primary Sponsor: Senator Melony Griffith
Effective Date: July 1, 2021

Provides authorization to reimburse healthcare providers for telehealth practice

- Defines healthcare providers as "licensed, certified, or otherwise authorized under the Health Occupations Article to provide health care in the ordinary course of business or practice of a profession or in an approved education or training program."
- Defines telemedicine as it relates to the delivery of health care services, that usesinteractive audio, video, or other telecommunications or electronic technology to deliver a health care service that is within the scope of practice of the health care provider at a site other than the site at which the patient is located and that enables the patient to see and interact with the provider
- Telemedicine does not include email, phone call or fax
- MDH may authorize payment for services for telehealth and may specify which healthcare providers are eligible for reimbursement
- If MDH makes regulations for reimbursement, primary care providers, psychiatrists and psychiatric nurse practices providing specified services shall be reimbursed
- The bill goes in more detail about the types of services that can be provided. Pharmacists are included in the definition of healthcare providers who may practice telehealth, it would be up to MDH as to whether the services would be reimbursable.

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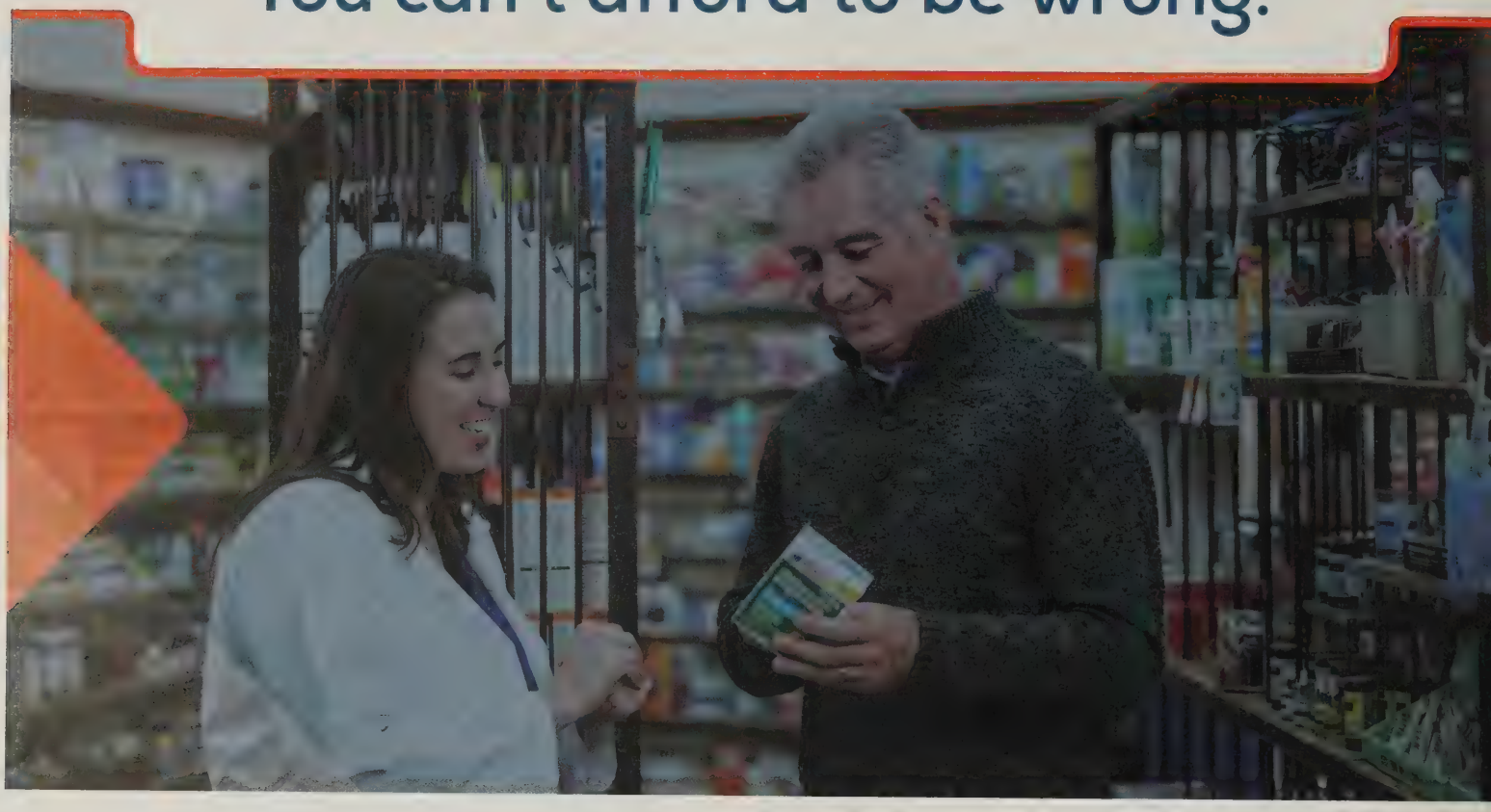

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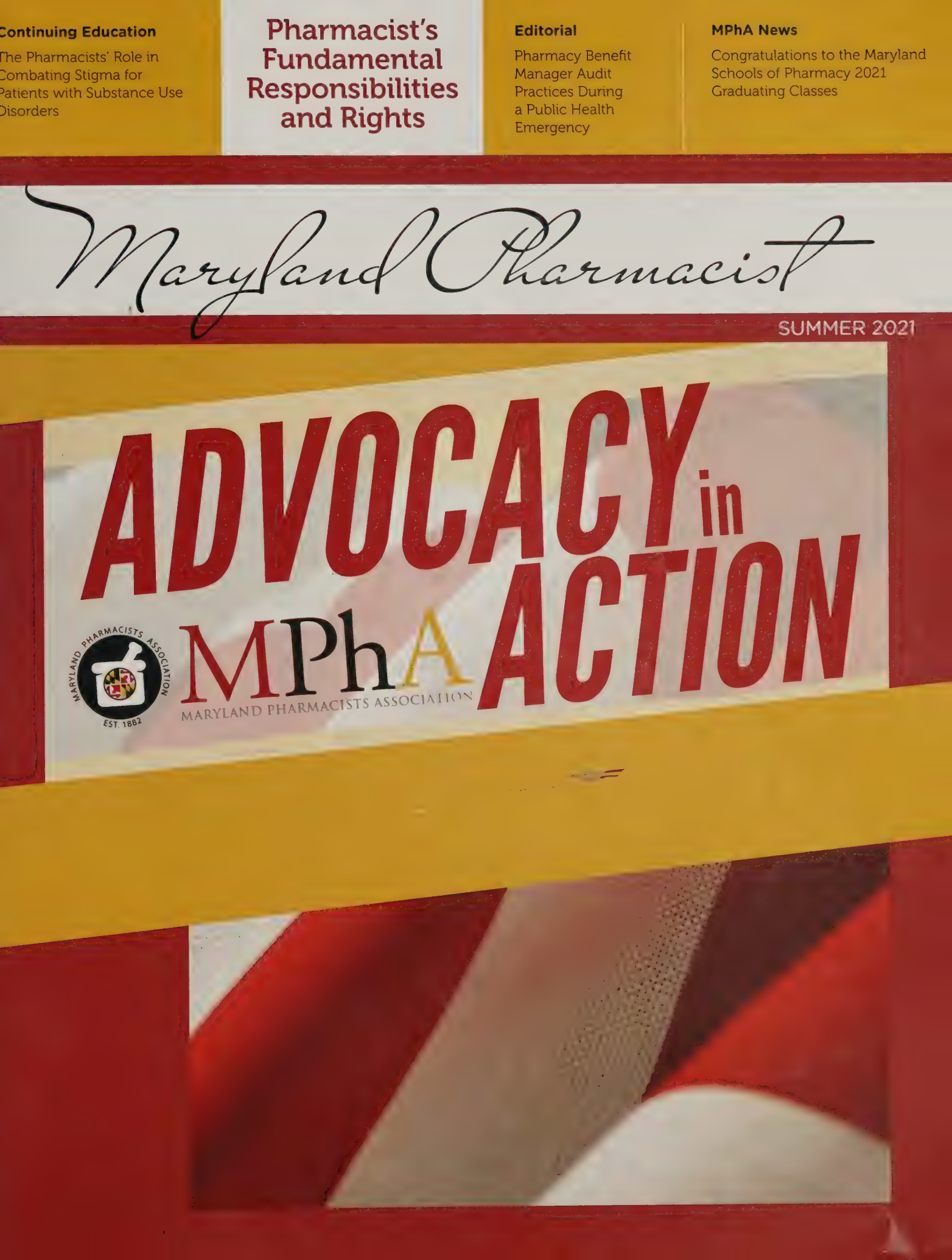

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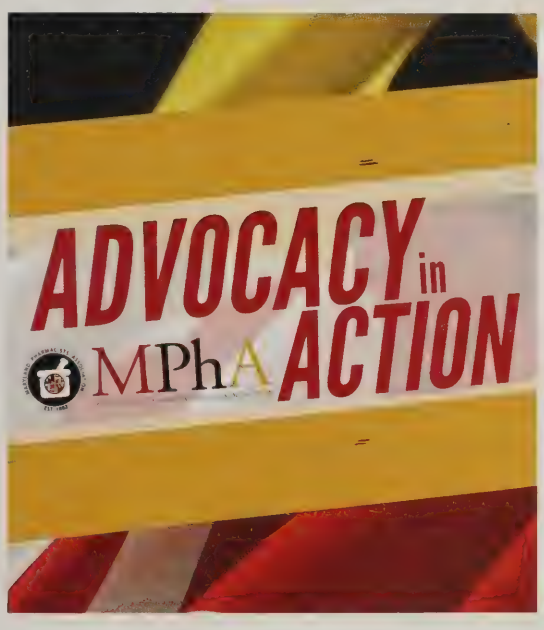
Contents

COVER STORY

Advocacy in Action

The boards of APhA and NASPA have released principles that outline the fundamental responsibilities and rights of pharmacists in workplace settings, to enable pharmacists to fulfill their professional responsibilities while serving their patients. The MPhA Board of Trustees has endorsed this document.



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Thank You to the MPhA Interns!

Shannon Weathers
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Sakeena Kazmi
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Maryland Pharmacists Association, 9115 Guilford Road, Suite 200, Columbia, MD 21046, call 443.583.8000, or email aliyah.horton@mdpha.com.

President's Pad

Since last spring, we have been experiencing a period without comparison in recent memory. There was a clear call to action for healthcare professionals across the globe, and right here in Maryland. I am proud to say our members stepped up and answered the call in many ways, including everything from direct patient care in the hospital setting, to being a friendly ear or a shoulder to cry on.

Despite the difficulties we've faced, MPhA has continued to move forward through the work of the board, staff, volunteer leaders, and engagement of our members. Earlier in 2021, we put into place several policies we will be able to use for future advocacy, as well as completing future strategic planning to set us up for success. We have identified four strategic priorities to best lead MPhA into the future: diversity, equity, and inclusion; fiscal stability; proactive leadership in pharmacy practice; and MPhA first for our pharmacy community.

We have identified four strategic priorities to best lead MPhA into the future: diversity, equity, and inclusion; fiscal stability; proactive leadership in pharmacy practice; and MPhA first for our pharmacy community.

Annual Convention attendees provided myself and Chris Charles, our incoming president, feedback about what they as members would like to see in these categories, and we will continue to look for member and committee input as we continue to develop plans to deliver on each of these priorities.

Despite the need to stay physically distanced, our members still found ways to advocate for our profession. Examples include participating in the MPC Virtual Legislative Day and sharing stories with the public to illustrate how we can care for our patients and communities. Due in part to this increased awareness, MPhA had some big legislative wins this cycle, including the following bills that were passed:

- **HB 135/SB 84 —** authorizes pharmacists to administer long-acting injectables for chronic conditions.
- **HB 1040 —** extends the emergency order related to pediatric vaccinations with caveats and includes a study of implementation.
- **HB 601 —** PBM-related bill to amend state law to be in line with the outcomes of the PCMA vs Rutledge Supreme Court decision.

What I am most proud of is how I have seen pharmacists and pharmacy teams come together to work toward a common goal of protecting our communities through vaccination and preventative measures and treating patients in acute and outpatient settings. I want to thank all our 2020–2021 Board of Trustee members for their service during this time, and for helping to continue the work of the association during these unprecedented events. I also want to thank our volunteer leaders, without whom we would not have been able to deliver the services and programming our members rely upon. It has been my honor to serve as your president this year, and I am very excited to see what MPhA members accomplish next!

Kerry Cormier

Kerry Cormier, PharmD
MPhA President 2020-2021

MPhA Welcomes OUR NEWEST MEMBERS

MARYLAND PHARMACISTS ASSOCIATION

Welcome to MPhA: If you meet these new members, please welcome them to the MPhA Pharmily and be sure to invite them to join a committee or attend a networking event!

Engaged

Dale Morton – Rockville
Jami Butz – Lutherville
Jessica Boh – Lexington Park
Michael Findley – Baltimore

Informed

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Heaven Thomas – Rawlings

Students

Abena Ankomah, Columbia – Shenandoah University
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Aminah Jones, Belcamp – UMB
Andrew Pikounis, Baltimore – UMB
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Arit Ntekim, Bowie – UMB
Ashley Osores, Gaithersburg – VCU
Benson Sanga, Hyattsville – UMES
Bela Pandya, Pasadena – UMB
Breah Johnson, Baltimore – UMB
Brittany Gray, Baltimore – NDMU
Brittany Wentzel, Pasadena – Shenandoah University
Caitlin Benkart, Montgomery Village – UMB
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Acknowledgements

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Thank you to our outgoing Board of Trustees for your years of service and dedication to MPhA. We appreciate all that you do for MPhA and the Maryland pharmacy community.

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A special thank you to James L. Bresette, PharmD and Richard D'Ambrisi, AA, CPhT for your outstanding years of service to the Maryland Pharmacists Association Foundation Board of Directors from 2018-2021.

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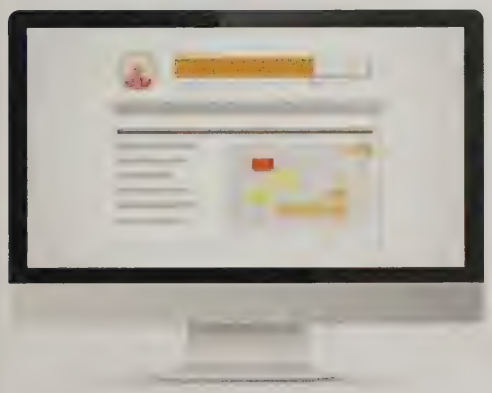

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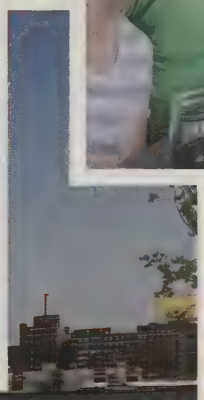
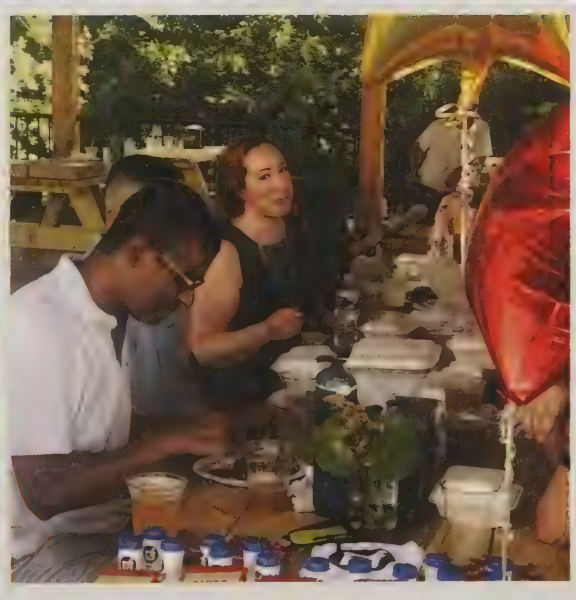
MPhA News

We Loved Seeing Our Pharmily in Person!

MPhA was thrilled to host several in-person social events surrounding the 2021 Annual Convention! Thanks to everyone who came out to network!





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Policies Passed by the MPhA 2021 House of Delegates

Emergency Preparedness and Response

1. MPhA supports all pharmacists, student pharmacists, and pharmacy technicians becoming members of the Maryland Responds Medical Reserve Corps as promulgated by the Maryland Department of Health with the purpose of receiving appropriate training and being able to be deployed when available wherever patient care services are needed during times of public health and other emergencies
2. MPhA supports the timely suspension of regulatory restrictions, practice limitations, and financial barriers as well as the expansion of pharmacy services to allow pharmacists to order and interpret the results of tests, expand the age range for pharmacist administered vaccinations and enjoy expanded liability protections during public health and other emergencies in order to meet immediate patient care needs.
3. MPhA supports allowing retired pharmacists whose licenses have lapsed to provide pharmacist services in emergency situations.
4. MPhA advocates for pharmacists' authority to ensure patient access to care through the dispensing, prescribing, administering of medications, as well as providing other patient care services during times of public health and other emergencies
5. MPhA encourages pharmacists to obtain all applicable training, software and equipment to ensure that they have the capability to perform telehealth/telemedicine/telepharmacy services during times of public health and other emergencies.

Comprehensive PBM Regulation

MPhA advocates for the creation of comprehensive regulations and statutes governing Pharmacy Benefit Managers (PBMs) that contract with pharmacies in the state of Maryland to ensure that all patients have access to essential pharmacy services.

Recommended changes include but are not limited to:

1. Requiring PBMs to be licensed in the state of Maryland
2. Restricting retroactive direct and indirect remuneration fees
3. Requiring PBM transparency and fair and equitable audits
4. Establishing a state oversight and enforcement authority that can impose penalties and fines for PBM violations of regulations ●

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Continuing Ed

The Pharmacists' Role in Combating Stigma for Patients with Substance Use Disorders

Bethany A DiPaula, PharmD, BCPP, FASHP, University of Maryland, Baltimore, Professor
Vanessa Clergeau, University of Maryland, Baltimore, PharmD Candidate 2022

Learning Objectives

After this activity, the pharmacist and pharmacy technician will be able to:

- Recognize how stigmatizing attitudes towards patients with substance use disorders can affect patient care
- Identify stigmatizing language commonly associated with substance use disorders
- Determine person-first alternative language, which can be employed by pharmacists in reducing stigma and supporting patients with substance use disorders
- Propose strategies pharmacists can use to reduce stigma for patients with substance use disorders

Keywords

Stigma, Substance Use Disorder, Barrier, Substance Related Disorders, Pharmacist

Background

The United States (US) continues to face an opioid crisis, which has been exacerbated by the COVID-19 pandemic. Overdose-related deaths are accelerating at an alarming rate with the largest number ever recorded for a 12-month period ending in May of 2020.[1] Based on results from the 2019 National Survey on Drug Use and Health, 20.4 million people aged 12 or older met the criteria for a substance use disorder (SUD) within the past year.[2] Over 21 million people required substance use treatment in the US with only 4.2 million receiving treatment.[2]

What Is Stigma?

Stigma can be defined as a label with an associated stereotype that elicits a negative response.[1,3] Commonly held stigma toward patients with SUDs include that they are dangerous, unpredictable, incapable of managing treatment, deserving of blame and punishment, and can stop at will.[3] Stigma can be further classified into subtypes.[4,5] Stereotypes of people with SUDs, like dangerousness, inform community opinions resulting in negative attitudes and what is known as public stigma.[4] With anticipated stigma, stigmatized individuals recognize the disparaging attitudes towards SUDs and expect to be rejected because of them, which can result in a desire to remain hidden.[4] Internalized stigma occurs when patients with SUDs accept the commonly held stereotypes as valid and can affect individual self-esteem.[4] Courtesy stigma is felt by friends and/or family as a result of a close association to an individual with a SUD.[4] Enacted stigma is the manifestation of public stigma and leads to discrimination and community desire for social distancing from individuals with SUDs.[4,5] Public and enacted stigma lead to structural stigma, which is how society constrains those with SUDs through cultural attitudes, laws, and policies.[4] An example of structural stigma is the punitive management of individuals with SUDs through the the criminal justice system, commonly known as the "war on drugs," as opposed to evidence-based treatment. Ultimately, these subtypes of stigma are interrelated resulting in poor health outcomes for patients.[4,5]

While there has been some progress in addressing stigma associated with psychiatric disorders such as depression and anxiety, SUDs remain highly stigmatized.[6] A World Health Organization (WHO) cross-cultural study of 14 countries found that "drug addiction" was the most stigmatized condition.[7] It is common for media outlets to promote stories about crime and violence associated with a SUD, which can perpetuate public and enacted stigma. However, it is not just the general community that have stigmatizing attitudes. The rate of stigma among healthcare professionals is also high. A national survey of primary care physicians found negative attitudes towards patients with prescription opioid use disorder (OUD) with a majority of respondents endorsing commonly held stigmatizing beliefs such as patients have personal responsibility for their illness and are more dangerous compared with the general population.[8] A second survey found that 33% of primary care physicians did

not perceive medications to treat OUD as effective.[9] Mental health providers also are affected by stigma. A survey of 516 providers attending a mental health, addiction conference noted that a case vignette which used the term "substance abuser" was significantly more likely to be associated with the perception of blame and deserving punishment compared with "substance use disorder."[10]

Moreover, pharmacy staff and students are not immune. A recent survey of community pharmacists noted that only 53% received SUD education in pharmacy school, and overall respondents held slightly stigmatizing attitudes towards persons with a SUD.[11] A second survey of pharmacists found that there was a desire for social distance and unwillingness to develop therapeutic relationships with patients with history of opioid misuse, especially with pharmacists who have practiced 10 or more years and/or lack personal experience with OUD.[12]

What Are the Ramifications of Stigma for Patients with SUDs?

Patients diagnosed with SUDs frequently report stigma as a major reason for reluctance to seek treatment.[13] In addition, stigma may increase the propensity to use illicit substances like opioids in isolation. Since naloxone is bystander administered, this puts individuals at greater risk for overdose related morbidity and mortality. Stigma influences provider perceptions and access to care. For instance, a provider might choose not to become waivered to prescribe buprenorphine/naloxone or a pharmacist might not stock buprenorphine/naloxone to avoid treating patients with OUD. Stigma also contributes to underinvestment in the treatment infrastructure as well as discrimination with insurance benefits, employment and housing.[4,5] For instance, state medicaid programs may require medication prior authorization and quantity limits, which can serve as barrier to care and leave patients at risk for withdrawal symptoms, relapse, and overdose.[4] Ultimately, stigma shapes public opinion favoring punitive versus health-oriented management of SUD.[4] Language frames attitudes about SUD and recovery, and it can also affect how individuals perceive themselves and their ability to respond to treatment. Most importantly, language intentionally and unintentionally propagates stigma.[14] When perceived societal stigma is internalized, it can result in loss of self-respect, decreased self-esteem, and loss of self-efficacy.[14] These feelings may harm the individual's outcomes and prognosis.[7]

Pharmacist's Role in Managing Patients with SUD

Pharmacists play a vital role in providing patient care, especially during the ongoing nationwide opioid crisis. The COVID-19 pandemic has further worsened the emergency with lockdowns and social distancing leading to increased patient stress, limited access to care, and skyrocketing overdose rates. As one of the most accessible healthcare professionals, pharmacists are front-line workers who are critical in managing public health, particularly care for patients with OUD. They are highly respected and the last healthcare provider before an opioid is dispensed. Throughout the opioid crisis, pharmacists continue to provide harm reduction and treatment efforts such as dispensing evidence-based medications to treat SUDs, offering naloxone to reduce morbidity and mortality

Table 1: Steps Pharmacy Staff Can Take to Combat Stigma Towards Patients with SUD and Optimize Care

Be familiar with common stigma and myths associated with SUD
Attend ongoing education regarding management of patients with SUD
Share resources with to combat stigma with healthcare providers and patients • Maryland Addiction Consultation Services (MACS) 855-337- 6227, www.marylandmacs.org (Healthcare Providers) • "Before It's Too Late" https://beforeitstoolate.maryland.gov/resources-2/ (Healthcare Providers and Patients/Community)
Use only person-first and recovery-oriented language. Avoid language which perpetuates negative stereotypes and/or slang
Listen without judgement and treat all individuals with dignity and respect
Understand that a SUD is a chronic relapsing brain disease and discuss patient care with colleagues using medically appropriate terminology
Recognize the role for evidence-based pharmacotherapy in treating patients and educate patients about benefits
Understand that treatment is individualized for each patient with no predetermined duration
Routinely offer care for patients with SUDs by stocking naloxone and medications to treat SUDs (such as buprenorphine, naltrexone) and screening and educating, as warranted

Table 2: Recommendations for Nonstigmatizing and Clinically Accurate Language to Reduce Stigma[3]

Terms to Avoid	Alternatives	Explanation
Patient Care Terms		
• Addict • User • Substance or Drug Abuser • Junkie • Alcoholic • Drunk • Substance Dependence	• Person with opioid use disorder • Person with alcohol use disorder • Person with substance use disorder • Person with opioid addiction • Person in recovery	• Person-first language • Shows that a person "has" a medical problem, rather than "is" the problem • Avoids negative associations, punitive attitudes, and blame • The term "abuse" was found to have a high association with negative judgments and punishment.10
Habit	• Substance use disorder • Addiction	• Implies a choice • Undermines severity of the disease
Abuse	*For illicit drugs:* • Use *For prescription medications:* • Misuse or used other than prescribed	Associated with negative judgments/punishment
Clean vs Dirty	*For toxicology screen results:* • Test negative/positive for specific substances *For non-toxicology purposes:* • Being in remission or recovery • Abstinent from drugs or alcohol • Person who uses drugs	Accurate terminology consistent with a medical disorder
Treatment Terms		
Methadone clinic	Opioid Treatment Program (OTP)	Accurate terminology. OTPs offer treatment with various evidence-based medications not just methadone
• Opioid Substitution Therapy • Opioid Replacement Therapy	• Opioid agonist therapy • Medication to treat OUD (MOUD) • Pharmacotherapy	Avoid misconception that medication is substitute for another drug/addiction
Medication Assisted Treatment (MAT))	• Medication to treat OUD (MOUD) • Pharmacotherapy • Medication for Addiction Treatment	"Assisted treatment" • undervalues the role of medication • unlike other medical disorders

associated with overdose, providing sterile syringes to prevent disease transmission, screening for SUDs using validated tools, monitoring for diversion with prescription drug monitoring programs, and providing patient education and treatment referrals. It is imperative for pharmacists to be educated about SUDs. Pharmacists are well positioned to address stigma directly as well as teach students, society and other healthcare providers about stigma associated with SUDs.

What Can Pharmacists Do To Address Stigma?

The first step in combating stigma is awareness. Table 2 provides an overview of actionable efforts pharmacists can make to address stigma. When providing care, it is important to listen to patients without judgment and treat everyone with dignity and respect. Pharmacists should be patient-centered when managing all patients, especially those diagnosed with SUD. Routinely using person-first and recovery-oriented language is essential in caring for this patient population.[14] Person-first language is where the person is differentiated from his or her diagnosis eliminating language that equates the individual with a disease state.[3] For instance, pharmacists provide patient care for a person diagnosed with OUD versus for a "drug addict." The pharmacist should avoid negative terms or slang such as "drug habit" or "junkie" which perpetuate stereotypes and stigma.[10]

Substance Use Disorder is a Disease

SUD or addiction is a chronic relapsing brain disease. The American Society of Addiction Medicine defines addiction as "a treatable, chronic medical disease involving

complex interactions among brain circuits, genetics, the environment, and an individual's life experiences. People with addiction use substances or engage in behaviors that become compulsive and often continue despite harmful consequences."[15] While genetic, developmental, psychiatric, and social factors affect susceptibility, these are all outside of an individual's control.[6] Patients should be assessed with validated scales and diagnosed using criteria for SUD as defined in the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5).[16]

Various resources are available to pharmacists on combating stigma. "Before It's Too Late" is a State of Maryland website that provides handouts and public service announcement videos for patients.[17] The Providers Clinical Support System (PCSS) offers resources for healthcare professionals on OUD and other SUDs including a free continuing education program on stigma.[18] In addition, the Maryland Addiction Consultation Services (MACS) provides support to pharmacists in addressing the needs of patients with SUDs and chronic pain management. Pharmacists can contact MACS's free phone consultation service with questions regarding medications to treat SUD, dosing, or insurance issues. Pharmacy staff can also request educational programming on SUD and/or chronic pain management. Please refer to Table 1 for additional resources.

Management of Substance Use Disorders

Evidence-based medications are the gold standard of treatment of SUDs, such as OUD. For example, methadone, buprenorphine, and naltrexone have been shown to be effective in reducing opioid use and preventing relapse. Pharmacists should routinely stock these medications and be well versed in dosing and side effects. It is important to understand that treatment duration is patient specific. There is no single length of treatment or required limit. Patients with a SUD respond to treatment and lead productive lives, but it can take time.[14]

Using medically appropriate and accurate words is critical in reducing stigma. For instance, the results from urine toxicology screens are often referred to as "clean" or "dirty." The medically accurate alternative would be a urine toxicology screen that is positive for buprenorphine and negative for other opioids. The term "opioid substitution therapy" was commonly used in the past in reference to opioid agonist treatment (methadone, buprenorphine). However, this wording conveys the incorrect message that we are simply substituting one addiction for another. "Medication assisted treatment" is also commonly used to refer to medications to treat OUD and other SUDs. However, "assisted treatment" implies that these medicines are unlike evidence-based treatment employed for the management of a chronic medical disorder. More accurate and appropriate terminology would be *medication treatment, pharmacotherapy, or opioid agonist treatment*.

Conclusion

In conclusion, every patient deserves respect and treatment without judgment. Pharmacists work directly with the community and have a duty to provide optimal care for all patients. Pharmacists and technicians need to be aware of how stigmatizing language can affect people with SUD and treatment outcomes. Using medically appropriate terms is essential when managing patients. In addition, it is important to be knowledgeable about resources that can be shared with the community to help combat stigma. Pharmacy students and staff should receive ongoing education about evidence-based management of SUD to provide optimal care. Additional evidence-based research on how to effectively combat stigma and improve outcomes could serve to further improve patient outcomes.

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Active Learning Patient Case

A 30-year-old Caucasian (RB) was recently diagnosed with substance use disorder (SUD) by her primary care physician (PCP). She was prescribed oxycodone 15 mg every 6 hours as needed for her moderate to severe back pain secondary to a car accident 6 months ago. The patient started to consistently request early refills due to increased frequency of use, taking larger amounts than prescribed, and no longer feeling pain relief from prescribed dose. She completed her prescribed quantity 2 weeks early, and her request for a new prescription was denied due to her PCP's concerns of inappropriate use. She states that at that point she began purchasing heroin from other people to satisfy her cravings. She is now concerned about her opioid use and wants to seek help.

She feels shame about this and when she told her husband about her use, he became upset and angry, which has caused her to feel completely isolated. She has many friends and family in the medical field, and knows they have strong negative views towards "drug users." She feels extreme guilt and embarrassment about her condition, and states she was in denial for months about her condition. Her last heroin use was a few hours ago. She was reluctant to receive treatment for SUD. She has heard that it doesn't work and doesn't want to "get hooked" on another medicine. Her physician sent an electronic prescription for Suboxone to your pharmacy. She notes that she would like to go to a daily treatment program for accountability and regular treatment. And she desires a smooth process without severe withdrawal symptoms. Today, RB presents to her local pharmacy to pick up Suboxone but feels overwhelmed.

1. **RB asks: "What is Suboxone for?" How do you respond?**
   a) It is an opioid substitution or replacement therapy
   b) It is a drug for addicted people
   c) It is an opioid agonist treatment for SUD
   d) It is evidence-based treatment for opioid use disorder (OUD)
   e) C and D
2. **Given the patient's stated goals of therapy, which of the following is the best treatment option?**
   a) Methadone
   b) Naloxone
   c) Naltrexone
   d) None of the above
   e) All of the above
3. **Which of the following actions by the pharmacist or pharmacy staff could deter RB's recovery?**
   a) Using stigmatizing language about SUD
   b) Refusing to fill the medication because of beliefs that Suboxone is not effective or ethical
   c) Dispensing the medication and counseling on Suboxone dosing and monitoring
   d) A and B
4. **What effects did RB experience from internalized stigma?**
   a) Psychological distress
   b) Prolonged untreated SUD
   c) Reduced engagement with substance use treatment
   d) All the above

Answers on page 17

CONTINUING EDUCATION QUIZ

Note: Instructions for obtaining your CE has changed. Please contact MPhA Headquarters if you have any questions.

The Virginia Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

MPhA Members may retrieve FREE CE for this article up to one year after the program release date.

Initial Release Date: 7/14/2021

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The authors have no financial disclosures to report.

This program is Knowledge Based — acquiring factual knowledge that is based on evidence as accepted in the literature by the health care professionals.

Directions for taking this issue's quiz:

To receive CE credit for this activity, participants must read the article in its entirety, complete an evaluation survey on the activity, and earn a grade of 70% or higher on a short exam.

This issue's quiz on **The Pharmacists' Role in Combating Stigma for Patients with Substance Use Disorders** can be found online by scanning the code below or go to: https://www.lecturepanda.com/r/PharmacistsRoleInCombatingStigma-SUD:

(1) Enter your name and contact information.

(2) Take the quiz and click "Complete Quiz."

Explained Answers (Patient Case)

1. **Answer E** — Suboxone is an opioid agonist treatment **[Answer C is correct]** and helps prevent painful symptoms of withdrawal **[Answer D is correct, therefore the correct response is E]**. There is a misconception that Suboxone and Methadone merely "substitute" one drug or one addiction for another *[Answer A is incorrect]*. Patient-first language would include describing people as having an addiction, not being "addicted" *[Answer B is incorrect]*.

2. **Answer A** — Methadone is a full opioid agonist that requires patients to go to licensed opioid treatment program daily to receive medications. **[Answer A is correct;** *Answer D is incorrect]*. Naloxone is an opioid antagonist used to manage opioid overdose *[Answer B is incorrect; Answer E is incorrect]*. Naltrexone is an opioid antagonist that will precipitate withdrawal and would not be a good option for a patient with recent opioid use *[Answer C is incorrect]*.

3. **Answer D** — The language we use is powerful and refusing to dispense a medication or using stigmatizing language during dispensing are barriers that can negatively impact a patient's recovery **[Answer A and Answer B are correct, therefore Answer D is the correct response]**. Dispensing Suboxone and educating is within the pharmacy scope of practice and is an effective means to improve patient adherence so this would not be an issue to recovery [Answer C is incorrect].

4. **Answer D** — Internalized stigma can cause many negative effects. RB's experienced depression, isolation, shame **[Answer A is correct]**. These feeling caused her to avoid engaging in care for her SUD **[Answers B and C are correct]**, therefore **[Answer D is the correct choice]**.

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Editorial

Help! Audited Prescription is Waiting for Pickup

Trenton Thiede, PharmD, MBA, President at PAAS National®
Expert Third-Party Audit Assistance and FWA/HIPAA Compliance

Over the last few years, there has been an increase in the number of PBMs auditing prescriptions within the current billing cycle. These are often desk audits containing one or two prescription claims. Many of these audits will request a copy of the prescription as well as the signature log. This creates confusion on how, and when, to respond to the audit if the prescription is still waiting to be picked up.

Here is a recent example of a Prime Therapeutics audit to illustrate this point:

1. Claim submitted January 12, 2021
2. Desk audit received January 13, 2021 – request for prescription + signature log
3. Pharmacy call to PAAS National® on January 18, 2021 – prescription not dispensed as of this date
4. Response deadline January 27, 2021

What Should the Pharmacy Do?

Option 1 — respond immediately; submit a copy of the prescription with a note that the prescription has not yet been dispensed

Option 2 — wait to respond until the prescription is dispensed; then send a copy of the prescription and signature log

Note: Prime Therapeutics has a 14-day return to stock requirement. Therefore, if the prescription is NOT dispensed by January 26, the pharmacy should reverse the claim and send copy of the prescription plus a note that the medication was not picked up and the claim has been reversed.

PAAS Tips

- Submit the requested documentation that exists at the time of your response.
- If one of the requested documents has not yet been created (i.e., a signature log), then include a note to the auditor explaining why this document is not included.
- There is no extra credit for responding to audits early.
- Pharmacies must respond to all PBM audits (even if claims have been reversed).
- If you find a billing error prior to response, contact the auditor for direction as some audits explicitly indicate it is acceptable to resubmit claims, while others say the exact opposite.

Editorial

Pharmacy Benefit Manager Audit Practices During a Public Health Emergency

Stacy Wilk, Communications and Marketing Manager at PAAS National®

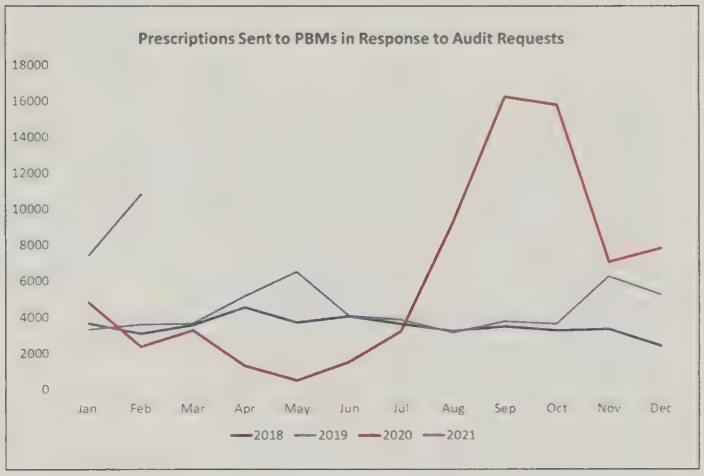
PAAS National® works with many community pharmacies impacted by the pandemic and sees firsthand the burden placed on their businesses and patients they serve. Many pharmacies have had to close their front-end, adapt to curbside pickup, expand delivery service, add labor, and/or invest in partitions – the list goes on. Pharmacy Benefit Managers (PBMs) gave some reprieve on audits during the initial months of the Public Health Emergency, but those concessions were short lived as PBMs devised a new way to recoup money from community pharmacies.

"Pharmacists have stepped up to provide point-of-care testing, COVID-19 vaccinations, and be an endless resource for communities in a desperate time of need," stated Trent Thiede, President at PAAS National, "With vaccinations in full swing, priorities should be focused on serving patients and our communities, not responding to audit requests."

Onsite audits continue to be suspended; however, PBMs have created virtual audits to take their place. These virtual audits require pharmacies to do a lot more work than a traditional onsite audit. Pharmacies need to gather prescriptions, signature logs, and credentialling documents to make copies and submit to the PBM; and that is just the start of the audit. The auditor has no travel time or time spent in the pharmacy and can; therefore, audit more prescriptions.

Prior to 2020, PAAS National® saw an average increase in the number of audits, year-over-year, of 12.8% (5-year average). Against that prevailing trend, audits declined in 2020 by 13.9% overall; however, the numbers here do not tell the whole story. With the shift to virtual audits, pharmacies were required to submit 40% more prescriptions in response to audits, as compared to 2019 (excludes onsite audits). The top 10% of audits averaged more than 80 prescriptions (up 38% from 2019). Consequently, the average initial audit results rose to $23,978, a 35% increase over the 5-year average. It is clear PBMs are looking to make up for lost time/revenue and continuing to audit pharmacies struggling to keep up with pandemic demands.

If you would like more information about our experience with helping community pharmacies with PBM audits, please call PAAS National at (608) 873-1342, or email info@paasnational.com.



Prescriptions Sent to PBMs in Response to Audit Requests 2018-2021

PAAS National® has helped community pharmacies since 1993 in their dealings with Pharmacy Benefit Managers (PBMs) and, in particular, pharmacy audits, filling and billing questions, contract analysis and FWA/HIPAA Compliance. Representing more than 5,000 community pharmacies nationwide, PAAS has analyzed over 80,000 audits and assists members in all 50 states and Puerto Rico. PAAS has helped member pharmacies save over $835 million in audit recoupments and achieve peace of mind knowing they are in good hands.

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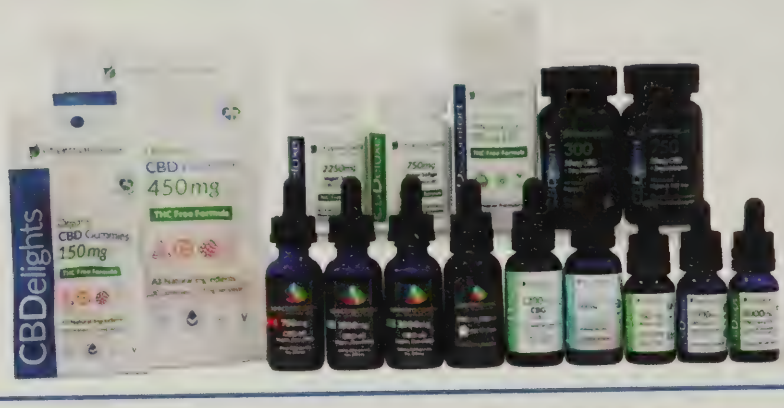

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Editorial

'Mr. Pharmacy' — Mel Rubin

By Neil S. Rubin

"You should have seen her face lit up," Melvin N. Rubin, told an interviewer through the tears in September 2005 about a little girl he had met. "She lost everything, so I gave her a doll; your daughter has them by the dozen."

He was just back from New Orleans, La., where he headed the pharmaceutical arm of the state's emergency response team in the wake of Hurricane Katrina. For more than five decades, it was one of his countless volunteer efforts in the name of pharmacy.

Rubin, 87, died in Baltimore on May 3, 2021. Known by many as "Mr. Pharmacy," the moniker came from a seemingly endless array of roles over a career that stretched from the craggy Turkish-Soviet border mountains to the slopes of Arbutus's Maiden Choice Lane, the latter where he co-owned J & S Paradise Pharmacy. In that small neighborhood store, customers would come from a more than 200-year-old Black convent, future Gov. Robert Ehrlich's family and a continual stream of heads popping in to update "Doc" on their lives.

His array of titles and honors included: president, MPhA (1976-77); MPhA honored alumnus (1980); BMPhA president (1974); State Pharmacy Board member (8 years); four Governor's Citations for "outstanding" and "exemplary" service; and helping to write questions for the national boards.

There were painful times as well. As MPhA ethics chair, he took licenses from some friends — then strived to help them find alternative employment.

Born March 20, 1934, in Baltimore's Sinai Hospital, Rubin was raised in the 900 block of East Baltimore's Gay Street; he fondly remembered playing in the alleys behind the family watch repair and jewelry store. After Baltimore City College High School, he graduated in 1955 from the U of M School of Pharmacy. Military service then took him to a U.S. base atop a mountain in Turkey. He confessed to more fear of drunken Turkish soldiers guarding the base — who randomly shot at it — than the nearby Soviets and their missiles.

After honorable discharge came time with the Read's chain. By the early 1960s, he had bought into Paradise Pharmacy, partnering with soon-to-be lifelong friend John Strauch. In those early days, one could find penny candies not far from 25-cent brown glass bottles filled with Coke syrup for upset stomachs. On a typical day, he would remind a doctor that a patient's new Rx would not mix well with existing ones, make a silly bet with workers on the Orioles, and tell his son — the writer of this article — to take a prescription next door to Shook's Bar & Lounge for "Mr. Jones, sitting on the second barstool."

By the mid-1990s "retirement" arrived, which meant two more decades in area seniors' community pharmacies, prepping colleagues for state inspections and helping to supervise nursing home mail-order pharmacies.

His humor? Well, teens called — certain they had invented the gag — to ask if the store carried Prince Albert in a Can (tobacco). A "yes" response was certain to bring a guffaw and "Then let him out!" So Rubin replied, "Hold on; I'll look." A few minutes later: "Hang on, I want to check downstairs." In yet a few more minutes: "There's one more place to look."

Eventually, the frustrated teens hung up, learning a core life lesson: don't prank the prankster.

His commitment to customers was legendary. In the late 1970s, a blizzard dumped two-feet of snow, but he left for work anyway. Ninety minutes later, an angry Rubin returned home. "I got to the Beltway [four miles away]," he said, shaking his head, "and the State Police wouldn't let me on! I told them pharmacies are open during a state of emergency, but they wouldn't listen!"

Through a life of doing, generations listened, learned and were inspired. ●

Rubin is survived by his wife, Phyllis (nee Sindler) Rubin, son Neil S. Rubin and daughter Stephanie D. Rubin Charanis.

Pharmacist's Fundamental Responsibilities and Rights

APhA and NASPA Collaborate in Development of Document to Facilitate Discussions for Change

The American Pharmacists Association (APhA) and the National Alliance of State Pharmacy Associations (NASPA) have released the Pharmacist's Fundamental Responsibilities and Rights (Fundamentals) for public comment. The Fundamentals principles focus on pharmacists' responsibilities and workplace expectations by addressing pharmacists' professional responsibilities as outlined in the Oath of a Pharmacist, the Pharmacist Code of Ethics, and scopes of pharmacy practice, along with addressing essential rights to which pharmacists are entitled so that their responsibilities can be fulfilled.

The Fundamentals principles reflect the issues of concern national and state pharmacy organizations have heard expressed by pharmacy personnel. The Fundamentals principles can be used to facilitate meaningful dialogue and action among pharmacists, pharmacy personnel, and pharmacy employers to enhance the pharmacy workplace and patient safety.

APhA American Pharmacists Association

THE PHARMACIST'S FUNDAMENTAL RESPONSIBILITIES AND RIGHTS

NASPA

Approved by the Boards of the
American Pharmacists Association and the National Alliance of State Pharmacy Associations (June 2021)
Supported by American Association of Colleges of Pharmacy (July 2021)

PREAMBLE

As members of the patient-centered health care team, pharmacists are accountable for the appropriate use of medications to treat acute and chronic conditions and population health-programs that work to prevent medication and health related misadventures. Pharmacists improve patient outcomes by assuming responsibility for:

- Appropriate use of medications using evidence-based guidelines.
- Facilitating achievement of patients' health and medication-related goals.
- Promoting prevention and wellness strategies that improve patient health and overall health outcomes.
- Designing and overseeing safe, accurate, and timely medication distribution systems.
- Providing high-quality, compassionate, cost-effective care.[1]

These principles and the document as a whole, prepared and supported by pharmacists, are intended to state publicly the fundamental rights that are essential to fulfill their professional responsibilities as outlined in the Oath of a Pharmacist and the Pharmacist Code of Ethics and states' scope of pharmacy practice. These principles are established to guide pharmacists in relationships with employers, patients, and health professionals; and, guide those individuals responsible for establishing federal and state laws/regulations/guidance that govern pharmacy practice and healthcare delivery. These principles were developed as a tool to initiate and facilitate conversations between pharmacy staff and their employers.

PRINCIPLES

PHARMACISTS HAVE THE FUNDAMENTAL RESPONSIBILITY:

I. To practice with honesty and integrity.

A pharmacist places the health and well-being of the patient and community at the center of their professional practice. A pharmacist has a duty to fulfill their professional responsibilities as outlined in the Oath of a Pharmacist, Pharmacist Code of Ethics, and scope of practice requirements.

"The Maryland Pharmacists Association (MPhA) is pleased to join with other national and state pharmacy organizations in asserting the Pharmacist Fundamental Workplace Rights and Responsibilities. We are also very proud that our very own Executive Director, Aliyah Horton, CAE was directly involved in the development of this important statement. MPhA has long supported and advocated for pharmacists' ability to serve their patients at the top of their training and licensure. As roles expand and pharmacists add additional patient services, adequate support from employers and colleagues is vital to ensuring both patient safety and pharmacists' wellbeing. I am overjoyed that MPhA endorses the Pharmacists Fundamental Workplace Rights and Responsibilities statement, and sincerely hope it will be a catalyst for positive change for pharmacists and patients in Maryland and around the country."

— W. Chris Charles, PharmD, BCPS, MPhA President 2021–2022

II. To seek employment that aligns with their professional goals and personal values and needs.

Pharmacists must be thoughtful when considering their personal professional goals, values, needs as they explore and review potential career opportunities. Pharmacists must also research and consider the work environment, values, and organizational goals of potential employers to understand how well they align with their own when evaluating employment opportunities.

III. To be lifelong learners to maintain professional competency and engage in the profession.

Recognizing that health care practice and therapeutics are constantly evolving, pharmacists have an obligation to pursue meaningful continuing professional development and education in order to maintain and optimize their clinical knowledge and abilities. Pharmacists must also have the support of their employer in order to pursue these opportunities.

IV. To educate their patients and the public to enhance public health.

Pharmacists are often the most accessible health care professionals in their communities and are essential to help educate patients to optimize use of their medications and achieve optimal health outcomes. Pharmacists bridge gaps in patient care throughout the health care delivery system. Pharmacists also play an active role in reinforcing consistent and reliable public health messages while helping to provide accurate health-related information to our patients in an era of abundantly available misinformation.

V. To make decisions and seek resolutions regarding workplace concerns without fear of intimidation or retaliation from their employer or supervisors.

Pharmacists have the responsibility to identify, address, and when needed elevate concerns regarding workplace issues that may compromise the safety, health or well-being of the pharmacy personnel or patients they serve. Employers and supervisors have a corresponding responsibility to encourage pharmacists and other pharmacy personnel to raise concerns about, and offer solutions to, maintain high-quality patient care and working conditions without fear of retaliation or intimidation from employers or supervisors.

PHARMACISTS HAVE THE FUNDAMENTAL RIGHT:

I. To practice pharmacy in the best interest of patient and community health and well-being.

A pharmacist must consider the rules and regulations intended to protect the health and well-being of patients and communities while also using professional judgment in their decision making process.

II. To exercise professional judgment under the auspices of their license when delivering care to patients.

Pharmacists must have the independence to use their education and knowledge to make professional clinical decisions in the best interest of their patients. To mitigate incidents of moral distress[2], pharmacists should never be placed in a situation where they are forced to take part in patient care activities or decisions that they do not believe are in the best interest of the patient's health and/or well-being or that are in violation of pharmacy laws and/or regulations.

III. To be treated in a considerate, respectful, and professional manner by patients and supported by employers and supervisors.

Pharmacists should not be subject to behavior or work conditions that impede their independent professional judgment, or actions that compromise the best interests of the health and well-being of their patients or their status as a healthcare professional.

IV. To a workplace free of racism, discrimination, bullying, or harassment, as well as physical, verbal, or emotional abuse.

Pharmacists' workplaces should be free of discriminatory practices including but not limited to, physical abuse, emotional abuse, verbal abuse, racism, discrimination, harassment, or bullying.

Continued on next page

V. To a working environment where the necessary resources are allocated to provide both legally required patient care services, as well as any additional enhanced patient care services offered.

Pharmacy is a highly-regulated profession which includes specific state and federal legal requirements that must be met when taking care of patients. At a minimum, sufficient time and adequate staffing are needed to safely adhere to the basic legal requirements before adding enhanced patient care services (e.g., vaccine administration, Medication Therapy Management (MTM), collaborative practice services). In addition, pharmacists should have ready access to current information and appropriate clinical and therapeutic references to support their delivery of patient care.

VI. To reasonable working hours and conditions.

Pharmacists must be permitted and encouraged to take needed breaks as well as sufficient, appropriate staff to safely complete the tasks at hand. Pharmacists should have access to tools when needed to promote and maintain physical and mental health (i.e., ergonomic work tools, stool or chair, cushioned floor mat when standing for long periods, appropriate lighting, access to appropriate restroom and lactation facilities, access to sustenance throughout the day).

VII. To have a voice in the development of metrics, and how those metrics are used as criteria for performance evaluations of all pharmacy staff.

Pharmacists should be evaluated fairly, with performance metrics and indicators that are focused on quality patient care while assuring adequate staffing is provided to meet those metrics and ensure patient safety by preventing medication errors. Meaningful performance metrics should address the quality of care provided to patients that pharmacists can directly impact and not only the cost or efficiency of services or operations. ●

REFERENCES

1 Based on the Joint Commission of Pharmacy Practitioners Vision for Pharmacy Practice (Adopted 2014).

2 In 1984, Andrew Jameton coined the term moral distress as the negative feelings a nurse feels when one knows the morally correct action to take but is constrained in some way from taking this action. It is different from burnout because it deals with your moral responsibility in a situation that you evaluate and determine the right course of action and then are prevented from doing it. The American Journal of Nursing (July 2016) suggests that moral distress can lead to "debilitating frustration, anger, and guilt." This article indicates that system-based sources of moral distress include "restrictive institutional policies, power structures, and regulatory practices, as well as limited human and material resources." Only in the last few years have publications explored moral distress in other health care professionals.

You can also view the full Pharmacists' Rights and Responsibilities document at https://bit.ly/3m3IVqC.

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Maryland Pharmacist

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President's Pad

Hello MPhA!

What an honor it is to address you in my first President's Pad. As I write to you all from my post deployed with a USPHS mission, I can't help but feel an overwhelming sense of pride and gratefulness. Pride in the pharmacy community for the unwavering commitment to your patients that you have shown for more than a year and a half of previously unimaginable challenges. Gratefulness to be counted among your honored ranks.

As our Past President Kerry Cormier shared in her outgoing message, pharmacists across the globe stepped up in an historic way over the past year and half. When the whole world shut down, toilet paper shelves emptied, and many parts of the health care sector closed their doors for a while or went virtual, pharmacists just masked up and continued providing critical care to their patients. Bravo Zulu!!

As the pandemic provided many opportunities to expand our scope of practice and highlight our impact, MPhA continues to rise to challenges that remain. In addition to tasking each committee with different aspects of our updated strategic plan, the MPhA Board of Trustees along with the Maryland Pharmacy Coalition have identified 3 advocacy focus areas for this year:

1) Provider Status/Payment Parity Legislation
2) Protect Immunization Authority
3) Support PBM Reform Bills

I invite you to help us advocate for these efforts, and to help ensure the success of our strategic plan by joining a committee or two that aligns with your particular interests. Many new MPhA leaders have stepped up this year; let's show them our support and rally beside them. Committee descriptions, charges, and committee chair contacts are located under the membership tab on our website.

As we talk about rallying together figuratively, I am excited to share that after a long yet necessary hiatus, MPhA is once again coming together physically! In-person gatherings have resumed as often as possible. So far MPhA has hosted a committee retreat, a student event, and a screening of Vaccination: The Misinformation Documentary. Board of Trustees meetings are open for all members to participate, and future events will be advertised in the Monday Message and our social media channels. Masks and social distancing are required for the time being, but nonetheless it feels so good to fellowship with many of you again.

The Maryland pharmacy community benefits greatly from seeing other pharmacists helping patients in innovative ways. We have a new Marketing Coordinator named Jenise Clark who stands ready to share all of the great ways Maryland pharmacists are providing care to their patients. If you provide or know of an innovative service or successful implementation of a recently authorized scope expansion, please reach out to Jenise at jenise.clark@mdpha.com.

Thank you again for all you do.

Very Respectfully,

W. Chris Charles, PharmD, BCPS
MPhA President 2021-2022

Member Mentions & News You Can Use

In Memoriam Brian and Kelly Robinette

We are deeply saddened by the senseless killing of Ellicott City pharmacist Brian Robinette and his wife Kelly. In October, during Pharmacists Month, we make an extra effort to celebrate the work of Maryland pharmacists and the tremendous care they provide to support their patients, community and broader public health goals. It pains us to know that Brian was targeted for this very work. Friends and family have set up a GoFundMe page to help support the couple's children. https://bit.ly/3HIG018

MPhA Board of Trustee Named Top 40 Under 40

Congrats to MPhA's V(i)P Deanna Tran, who was recently recognized as one of the Baltimore Business Journals' Top 40 under 40!

RALI CARES Trailer Tour

The Rx Abuse Leadership Initiative Maryland (RALI MD), of which MPhA is a founding partner, collaborated with CODE3 to bring signature RALI CARES educational programming to our membership via the RALI Cares Trailer. Del. Nic Kipke, House Minority Leader of the Maryland General Assembly offered greetings. Joe Abdalla a former law enforcement officer and Executive Director of CODE3 led us through a virtual tour of a teenager's/young adult's bedroom, which spotlights the hidden warning signs of substance misuse, particularly opioids. The tour is truly an eye-opening experience and a must-see for parents and caregivers. We recorded our tour and it can be found at https://vimeo.com/646145922.

Vaccination from the Misinformation Virus – MPhA Screening

As one of our first in-person member events, MPhA was pleased to host a screening of the PBS Documentary Vaccination from the MisInformation Virus. The documentary features several MPhA members and Notre Dame of Maryland School of Pharmacy (NDM SOP) leadership, faculty and students. What a great opportunity to have the work of our community highlighted and shared across the country! We hosted the screening prior to its release on local Maryland PBS stations. The one-hour documentary helps address vaccine concerns by explaining why they are safe. The documentary includes COVID vaccination, but addresses all vaccines explores the historical trauma behind vaccine hesitancy in many communities; why vaccines are safe despite digital misinformation; and the incredible work the medical and pharmacy professions are doing to confront the viral misinformation. It is a great documentary to share with friends and family as it explains how to overcome biases to understand why vaccines are 1) safe; 2) crucial to community health; and 3) save millions of people annually. Post-screening there was a panel with the producer/director Chris Schueler, Former Assistant Surgeon General RADM (ret) Pamela Schweitzer and Dean Anne Lin of NDM SOP. You may access the full documentary at www.pbs.org. For more additional information including short segments from the film and a free, downloadable curriculum guide, please visit: www.TheMisinformationVirus.com.

Call for Nominees – MPhA Board of Trustees

Interested in giving back to the profession? Providing leadership in Maryland pharmacy? If so, MPhA needs you! Nominations for 2022 MPhA Board of Trustees election are now open. The positions available include Vice President/President-elect and two Trustee seats. Trustees serve a three-year term. If you are interested in serving in this capacity and/or would like more information for next steps, please contact Deanna Tran, Nominating Committee Chair at tran.deanna@gmail.com.

Pharmacy Workplace Well-Being

The pharmacy profession knows that the well-being of pharmacy staff affects patient safety. While work has been done to identify and understand medication errors—including near-misses—and characterize the root causes, there is a lack of understanding—especially in peer research—about the workplace factors that affect this. To address this need, APhA and the National Alliance of State Pharmacy Associations (NASPA) have developed the Pharmacy Workplace and Well-being Reporting (PWWR) portal, a confidential and anonymous way pharmacy personnel can report positive and negative experiences in pharmacy practice as well as suggested solutions. MPhA's Executive Director, Aliyah N. Horton, served as a NASPA representative on the committee to deliver this product.

An individual's PWWR report will be collected and analyzed by the Alliance for Patient Medication Safety, a recognized and listed Patient Safety Organization, extending the strong confidentiality and privilege protections of the federal Patient Safety and Quality Improvement Act of 2005 to each report.

Only aggregated, non-identifiable data from all reports will be made available to qualified researchers for the purposes of education and the development of best practices and recommendations to enhance the pharmacy workplace. The PWWR submission portal is open to pharmacists, pharmacy technicians, and student pharmacists across all practice settings. It is available at any time; individuals can report as often as situations arise, and there is no deadline for submissions.

Access the portal here. https://www.pharmacist.com/Advocacy/Well-Being-and-Resiliency/pwwr

Note: The full *Pharmacist's Fundamental Responsibilities and Rights* principles was printed in *The Maryland Pharmacist* Summer 2021 issue.

MPhA Welcomes OUR NEWEST MEMBERS

MARYLAND PHARMACISTS ASSOCIATION

Welcome to MPhA: If you meet these new members, please welcome them to the MPhA Pharmily and be sure to invite them to join a committee or attend a networking event!

Engaged
Jordan Hines – Millsboro
Fufa Wami – Silver Spring
Jing Tassone
Rebecca Wong
Nora Lim
Tekalign Wondimu – Silver Spring
Shamika Brooks – Washington, DC
MichaelKent Findley – Baltimore

Informed
Sophie Soo – Gaithersburg
Sophia Park – Clarksburg
Amer Maksoud – Davie, FL
Betty Joffee – Baltimore
Negin Hadaegh – Silver Spring
Paige Gilk
Haley Evans – Deptford, NJ
Tamer Elhabibi
Dustin Dang – Elkridge
Eva Barany
Zahraa Mohammed – Owings Mills

Students
Christina David – Shenandoah University School of Pharmacy
Samichhya Paudel – Howard University College of Pharmacy
Jasmine Lee – University of Maryland Baltimore

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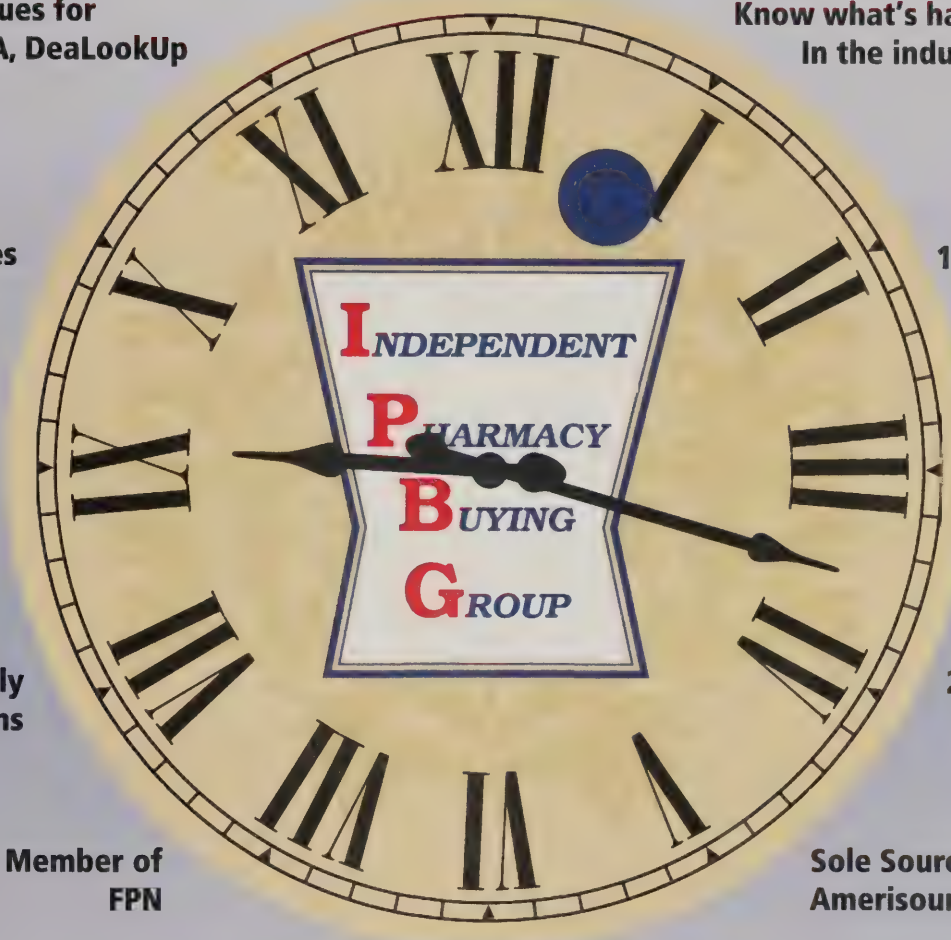

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It's MPhA Membership Renewal Season!

INFORMED, ENGAGED and CONNECTED members of the pharmacy community provide MPhA the power to continue to fulfill our mission to promote excellence in pharmacy practice, strengthen the profession of pharmacy and advocate for all Maryland pharmacists!

Do you want to be...

Informed

This will be a fantastic opportunity to build your network within the pharmacy community. The INFORMED members will receive the Monday Message, Advocacy Alerts and notices about MPhA events and products. Informed members will not have voting rights or receive member discounts.

Dues: FREE

Connected

This level provides all the benefits MPhA has to offer and recognition as being fully connected to your Maryland pharmacy community. Benefits include all the above plus continued delivery of the print Journal, member discounts on ALL products and services, access to invitation-only events and more. In addition, the dues will include the membership fee for the MPhA Foundation.

Dues: $250 (two memberships in one!)

Engaged

This level will take your engagement up a notch. The category includes all of the benefits from the Informed level plus voting rights, Maryland Pharmacist digital Journal, MPhA partner benefits and education discounts (at least $250 in savings).

Dues: $125

Technician

Technician benefits remain the same with the journal provided in digital format.

Dues: $25

Student

Student benefits remain the same with the journal being provided in digital format.

Dues: $10

Renew Now!

- Login to www.marylandpharmacist.org
- On the right hand side under My Profile , click on "Membership Info (Renew)" and follow the prompts to select your membership renewal options.
- If assistance is needed with logging in, please contact Jenise Clark at jenise.clark@mdpha.com or 443-583-8000.

For more information about group (five or more members) and corporate partner memberships, please contact Lauren Williams at lauren.williams@mdpha.com

Call for Nomination

MPhA Excellence in Pharmacy Awards

Nominations are Open!

Each year, MPhA recognizes individual professional excellence during the MPhA Annual Convention. Nominations are reviewed and selections are made by the Past Presidents Council. Upon selection, individuals will be notified in advance of the Annual Convention. Nominations for the 2022 Annual Awards are now open!

Learn more here: https://www.marylandpharmacist.org/page/AnnualAwards.

Bowl of Hygeia Award

sponsored by the American Pharmacists Association Foundation and National Alliance of State Pharmacy Associations

Established in 1958, the Bowl of Hygeia Award recognizes pharmacists who possess outstanding records of civic leadership in their communities and encourages pharmacists to take active roles in their communities. In addition to service through their local, state, and national pharmacy associations, award recipients devote their time, talent, and resources to a wide variety of causes and community service. Any MPhA pharmacist member who has not already received the Bowl of Hygeia Award is eligible for nomination.

Maryland Pharmacists Association Seidman Distinguished Achievement Award

This award was established by the Maryland Pharmacists Association to recognize an individual who has made major contributions to the Maryland Pharmacists Association, organized pharmacy, and the profession of pharmacy. Any MPhA pharmacist member who meet the criteria for this award is eligible for nomination. Current members of the MPhA Board of Trustee are not eligible for this award.

Excellence in Innovation Award

sponsored by Upsher-Smith Laboratories, Inc. and the MPhA Foundation

Established in 1993, this award (formerly known as the Innovative Pharmacy Practice Award) aims to recognize forward-thinking pharmacists who have expanded their practices into new areas. Any practicing MPhA pharmacist member within the geographic area who has demonstrated innovative pharmacy practice resulting in improved patient care is eligible for nomination. Current members of the MPhA Board of Trustees are not eligible for this award.

Distinguished Young Pharmacist Award

sponsored by Pharmacist Mutual Insurance Companies

This award is presented each year to a pharmacist who has graduated within the past ten years and has made a significant contribution to the profession through service to a local, state, or national pharmacy organization. Any MPhA pharmacist member who has graduated from a school of pharmacy within the last ten years is eligible for nomination.

Maryland Pharmacists Association Mentor Award

This award, established in 2004, recognizes individuals who encourage pharmacists, technicians, and/or student pharmacists in the pursuit of excellence in education, pharmacy practice, service, and/or advocacy. Any MPhA pharmacist member who meets the criteria for the award is eligible for nomination. Current members of the MPhA Board of Trustees are not eligible for this award.

Maryland Pharmacists Association Honorary President

An honorary position on the Board of Trustees is given to a person, not necessarily a pharmacist, who has worked for MPhA or Maryland Pharmacy over a long period of time. Any long standing contributor to the profession or the Association is eligible for nomination. Current members of the MPhA Board of Trustees are not eligible for this award.

Pharmacist Advocate Award

This award is intended to cover the breadth of work of a pharmacist's advocacy efforts and is not limited to the annual legislative process. The nominee must be a pharmacist who is a member of MPhA. The government affairs activity in which the nominee participated must have raised pharmacists' awareness of the political process, improved the pharmacy profession and the political process, and/or improved service and education to the patient. MPhA staff members, lobbyists, and state or federal officials are not eligible.Current members of the MPhA Board of Trustees are not eligible for this award.

Editorial

Financial Forum
Measuring the Value of a Financial Professional

Findings suggest that these relationships can make a difference for investors.

This series, Financial Forum, is presented by PRISM Wealth Advisors, LLC and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

What is a relationship with a financial professional worth to an investor?

A 2019 study by Vanguard, one of the world's largest money managers, attempted to answer that question.

Vanguard's whitepaper, concluded that when an investor works with a professional and receives that level of investment advice, they may see a net portfolio return about 3% higher over time.[1]

How did this study arrive at that conclusion?

By comparing self-directed investor accounts to this model, Vanguard found that the potential return relative to the average investor experience was higher for individuals who had financial professionals.[1]

Vanguard analyzed three key services that a professional may provide: portfolio construction, wealth management, and behavioral coaching. It estimated that portfolio construction advice (e.g., asset allocation, asset location) could add up to 1.2% in additional return, while wealth management (e.g., rebalancing, drawdown strategies) may contribute over 1% in additional return.[1] Asset allocation is an approach to help manage investment risk. Asset allocation does not guarantee against investment loss.

The biggest opportunity to add value was in behavioral coaching, which was estimated to be worth about 1.5% in additional return. Financial professionals can use their insight to guide clients away from poor decisions, such as accepting excessive risk in a portfolio. Indeed, the greatest value of a financial professional may be in helping individuals adhere to an agreed-upon financial and investment strategy.[1]

Of course, financial professionals can account for additional value not studied by Vanguard, such as helping clients implement wealth management strategies, which may help protect against the financial consequences of loss of income, and coordinating with other financial professionals on tax management and estate strategies. After years of working with a financial advisor, the value of a relationship may be measured in both tangible and intangible ways. Many such investors are grateful they are not "going it alone." ●

Pat Reding and Bo Schnurr may be reached at 800-288-6669 or pbh@berthelrep.com.

CITATIONS

1 - advisors.vanguard.com/iwe/pdf/ISGQVAA.pdf [2/19]

Save the Dates in your 2021-22 Calendar

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Board of Trustees Meeting	Board of Trustees Meeting	2022 MPhA Mid-Year Meeting

Continuing Ed

Common Drug Interactions with Urine Drug Monitoring

By Seferina Kim, PharmD, BCPS and Matthew Bathula, PharmD, BCPS, University of Maryland School of Pharmacy

Learning Objectives

After this activity, the *pharmacist* will able to:

1. List common substances tested with home urine drug monitoring (UDM)
2. Understand limitations of tests that use urine samples
3. List common medications that cause false positive results of UDM
4. Interpret the results of an over-the-counter UDM
5. Assist with appropriate follow-up laboratory monitoring recommendations

After this activity, the *pharmacy technician* will able to:

1. List common substances tested with home urine drug monitoring (UDM)
2. Understand limitations of tests that use urine samples
3. List common medications that cause false positive results of UDM

Keywords

Urine Drug Monitoring, Substance Abuse, Lab Interaction

Urine Drug Monitoring

Urine drug monitoring (UDM), or urine toxicology tests, are frequently used by hospitals, employers, and now patients to detect the presence of certain illegal or prescription drugs. The Food and Drug Administration (FDA) regulates the use of home urine toxicology tests by consumers and classifies them under in vitro diagnostic products.[1] Unfortunately, these tests are prone to medication interference and can result in false positive results. The purpose of this paper is to review the common drug-laboratory interactions associated with urine toxicology tests.

Types of Urine Drug Monitoring

Laboratories utilize chromatography with accurate and precise methodologies called gas chromatography-mass spectrometry (GC-MS), liquid chromatography tandem mass spectrometry (LC-MS/MS), or high-performance liquid chromatography (HPLC) to detect substances. These laboratory methods of chromatography separate molecules by their interaction with a carrier medium and then feed samples into a machine that detects molecules by their mass-to-charge ratio. Chromatography is a high cost process as it requires highly technical training and specialized equipment to complete. On the other hand, UDM is typically performed by providers or patients at point-of-care with immunoassay technology. Immunoassay technology uses antibodies to detect a predetermined amount of a drug and/or its metabolite in a sample. It is typically low cost, designed for easy use, and is non-invasive (as opposed to blood serum samples which require more invasive sample collection); however, has poor specificity and is prone to drug and food interactions. The results from an immunoassay can be gathered in a wide variety of settings but are limited exclusively to qualitative use and therefore cannot quantify the amount of drug in the sample. Unexpected results should always be confirmed by a laboratory utilizing GC-MS, LC-MS/MS, or HPLC.

There are several key differences between GC-MS, LC-MS/MS, and HPLC. However, for the purposes of this paper, any of these techniques are appropriate for confirmatory testing. It is recommended to review the packaging of your patients' UDM kit as some manufacturers offer chromatographic confirmatory testing with pre-paid mailers and lab slips at no additional charge while others do not.

There are many patient kits on the market from a wide variety of manufacturers (Table 1). These kits can differ in their testing methodology, though UDM is the most common method. Direct-to-patient UDM typically requires a minimum sample of 30 milliliters of urine collected in a cup, has little direct handling of urine, and provides results within minutes. Some manufacturers provide tests for a single substance while others test for several. The standard five substances tested for federal employment include amphetamines, cocaine, tetrahydrocannabinol (THC), opiates, and phencyclidine (PCP). Other substances commonly tested for

include, but are not limited to, barbiturates, benzodiazepines (BZDs), methylenedioxymethamphetamine (MDMA), nicotine, tricyclic antidepressants, and lysergic acid diethylamide (LSD). Of note, some kits claim 99% accuracy or higher while others do not state accuracy.

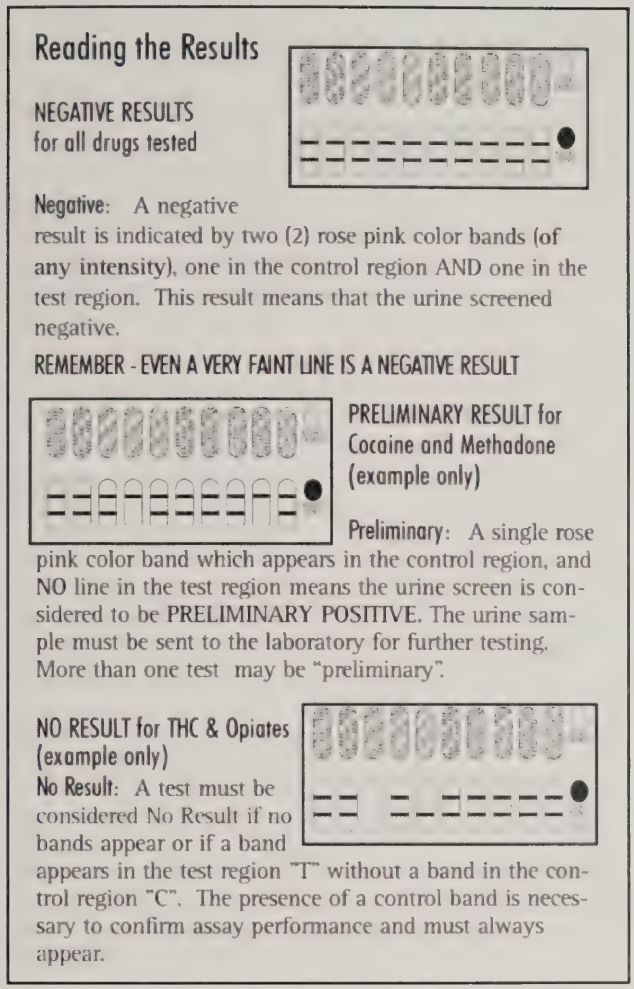
Table 1: Commonly Available Test Kits at Community Pharmacies in the United States and the Substances Assayed

	At Home™ https://www.athomedrugtest.com/	DrugConfirm® https://www.drugconfirm.com/	Equate™ https://www.confirmbiosciences.com/products/retail-brands/equate-home-drug-test/
Sample Tested	**Urine**	**Urine**	**Urine**
Amphetamine	X	X	X
Barbiturates	X	X	
Benzodiazepines	X	X	
Buprenorphine		X	
Cocaine	X	X	X
Codeine			
Heroin			
Hydrocodone			
Hydromorphone			
Methadone	X	X	
Methamphetamine	X	X	X
MDMA	X	X	X
Morphine			
Opiates	X	X	X
Oxycodone	X	X	
Oxymorphone			
PCP	X	X	X
Propoxyphene		X	
Tetrahydrocannabinol	X	X	X
Tricyclic Antidepressants		X	
Note: Not a complete list of patient drug testing products			

Interpreting Results of an Immunoassay

Pharmacists are front-line healthcare workers in the community setting that may be asked to review urine sample results and for assistance with interpreting results. Interpretation of direct-to-patient UDM utilizes immunoassay technology and requires close review of each manufacturer's insert. Here are some examples in the figures noted below:

Figure 1. QuickScreen: Result Interpretation



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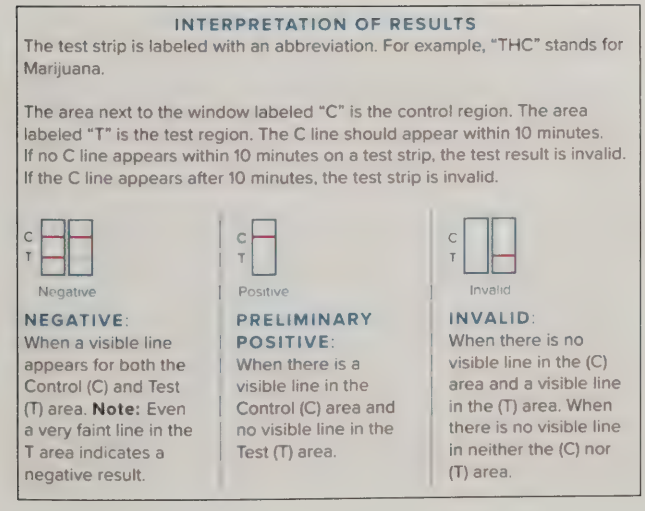
https://www.phamatech.com/wp-content/uploads/2016/07/At-Home-12-Panel-Test-Instruction-Question-Answer-Handbook.pdf

Figure 2: DrugConfirm Result Interpretation:



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https://www.drugconfirm.com/pdf/Instructions-1panel-TestCup.pdf

To reiterate, if there is a preliminary positive result, the pharmacist must counsel on the need for follow-up confirmatory testing to the patient. The pharmacist should review the manufacturer's packaging and assess options pre-built into the kit. If there are no options provided within the kit, the pharmacist should refer patients to their primary care provider to request a laboratory order for chromatography follow-up.

Common Medications That Interfere With Urine Toxicology Tests

Due to the lack of specificity of UDM, false positive results may occur as a consequence of food and medication interference. It is important to note that t he term opiate and opioid are not synonymous. Opiates refer to naturally occurring compounds including morphine and codeine. Opioids include all aforementioned naturally occurring compounds but also includes semi-synthetic, and synthetic derivatives such as heroin or methadone. This distinction will impact interpretation of results and can separate one kit from another when deciding which product to use. A thorough medication reconciliation performed by pharmacy staff will prove vital for pharmacist counseling and identifying interfering medications.

Pharmacy staff should verify the accuracy of the current medication list, including supplements, herbals, and over-the-counter medications. Pharmacists need to be aware of interfering medications in order to counsel patients prior to testing and for proper result interpretation.

The following is a list of common medications that have been associated with false positives utilizing UDM (refer to Table 2 for summary):

Bupropion is a common antidepressant prescribed for major depressive disorder, seasonal affective disorder, bipolar disorder, and smoking cessation. Bupropion undergoes metabolism via the cytochrome P450 isozyme 2B6 which results in active metabolites that inhibit the reuptake of dopamine, norepinephrine, and serotonin. These metabolites are structurally similar to amphetamines. A study from Casey and colleagues found 41% of false positives for amphetamines were attributed to therapeutic doses of bupropion in trauma patients admitted to the hospital.[2] Positive UDM results underwent confirmatory testing by GC to identify true false positive results. Another case report found a patient on bupropion tested positive for amphetamine and LSD.[3]

Trazodone is another common antidepressant but has many off-label uses, frequently being prescribed for sleep disorders, anxiety, and fibromyalgia. The mechanism of action predominantly involves inhibition of the reuptake of serotonin although it also has weak antagonist effects upon histamine and adrenergic receptors. While its molecular structure is not similar to MDMA, its metabolite, meta-chlorophenylpiperazine, has been known to be cross-reactive in immunoassays and is a cause for a false-positive for MDMA.[4] Of note, this metabolite has been identified in adulterated or counterfeit ecstasy tablets.[4]

Sertraline is a commonly used selective serotonin reuptake inhibitor frequently prescribed for a variety of mood disorders including depression and anxiety. Nasky and colleagues conducted a retrospective chart review from January 2007 to December 2008 and determined approximately 27% of false positives for benzodiazepines could only be attributed to the use of sertraline.[6] The unclear cross-reactivity with a variety of

reagents highlights the need for confirmatory testing and additional examination from immunoassay manufacturers.[6]

Venlafaxine and **desvenlafaxine** are serotonin norepinephrine reuptake inhibitors also used for depression and anxiety but may also be used for the treatment of certain pain disorders. Desvenlafaxine is the active metabolite of venlafaxine and neither parent compound or its metabolites carry structural similarities to PCP.[7] Case studies however, have shown that at both therapeutic and toxic doses, venlafaxine may cause a false-positive of PCP.[7-8] Additionally, a case report published in 2019 revealed a false-positive for PCP on therapeutic dosing for desvenlafaxine.[9]

Dextromethorphan is an antitussive that activates sigma opioid receptors in the cough center ultimately leading to an increased threshold for cough.[10] It has a molecular structure similar to morphine. While it does not have any analgesic properties or affinity for mu-opioid receptors, it is known to enhance the effect of morphine. When taken at higher doses, dextromethorphan acts similarly to PCP, binding to opioid receptors and PCP sites on NMDA receptors causing central nervous system and respiratory depression and inhibition of serotonin re-uptake, thus causing euphoria and hallucinations.[11] Per the Drug Enforcement Agency (DEA), dextromethorphan abuse is categorized into three plateaus: 100-200mg which may cause mild stimulation, 200-400mg which may cause euphoria and hallucinations, and 300-1500mg which may cause distorted visual perceptions and loss of motor coordination.[12] Maximum daily dose of dextromethorphan immediate or extended-release is 120mg.[10] The doses associated with euphoria may result in a positive urine drug screen immunoassay.[11] While the false positive generally appears for PCP, a positive opioid screen may also occur and should be further verified with additional testing.[12] Of note, if follow-up testing is negative for both opioids or PCP, the false positive with the initial urine drug monitoring may be indicative of dextromethorphan abuse.

Tramadol is a centrally-acting synthetic analgesic with multiple receptor targets in the noradrenergic, serotonergic, and opioid receptor systems, with its metabolite being a potent agonist for the mu-opioid receptor. Both the parent compound and metabolite are structurally similar to PCP and therefore will frequently cross-react with the immunoassay antibodies for PCP, thus causing a false positive.[13] These findings may occur even if patients do not appear to show signs of tramadol toxicity, which may include tachycardia, respiratory depression, and seizures.[14] There is also a possibility that tramadol may cause a false-positive for opiates, however, it is not likely as tramadol is synthetic.[13]

Efavirenz is a non-nucleoside reverse transcriptase inhibitor (NNRTI) selective for HIV-1 and prevents the polymerization of DNA from viral RNA and is frequently used in antiretroviral therapy. Structurally, the efavirenz moiety is similar to moieties on benzodiazepines.[15] Not surprisingly, both the parent drug and metabolites will frequently cross-react in the immunoassays for benzodiazepines and thus cause a false positive.[15] To a lesser extent, efavirenz may also interact with THC antibodies. It is theorized that the glucuronidated metabolite specifically cross-reacts and may also cause a false-positive for THC.[16]

Non-steroidal anti-inflammatory drugs (NSAIDs) are over-the-counter medications used for pain, inflammation, and fever. While rare, it was noted in one study of 510 patient urine samples taking varying levels of ibuprofen, naproxen, or fenoprofen, that two returned false-positive for cannabis and two returned false-positive for barbiturates. While this may not be clinically prevalent, it underscores the need to confirm any positive result from the immunoassay.[17]

Rifampin is a broad spectrum antibiotic commonly used for tuberculosis and non-mycobacterial disease. It was observed that after one dose of rifampin 600 mg, urine samples showed a false-positive for opiates.[18] This proved problematic in Spain, as noted in a *Letter to the Editor* to the "Journal of Analytical Toxicology" in 1995 that revealed that many local drug rehabilitation centers had patients with concomitant HIV and TB infections were being treated with rifampin tested positive for opiates.[19] The authors noted that many samples resulted positive by immunoassay but confirmatory GC-MS proved that many were false-positives.

Table 2. Common Causes for False-Positives Associated with Urine Drug Monitoring

	Amphetamines	Barbituates	BZD	LSD	MDMA	Opioids	PCP	THC
Bupropion	X			X				
Dextromethorphan						X	X	
Efavirenz			X					X
Sertraline			X					
Tramadol						X	X	
Trazodone					X			
Venlafaxine, Desvenlafaxine							X	
NSAIDs		X						X
Rifampin						X		

Implications

Many federal and non-federal workplaces require drug monitoring for employment as a condition of pre-employment and/or with annual physicals. Federal employers such as the Department of Transportation (DOT) and Department of Defense (DOD) exclusively use urine samples to test for five substances frequently referred to as the, "federal five", which include amphetamines, cocaine, cannabis, opiates, and PCP. Both the DOT and DOD require a combination of immunoassay with confirmatory testing by GC/MS at the Department of Health and Human Services-approved laboratories.[20,21] Per the Substance Abuse and Mental Health Services Administration (SAMHSA), employers are not required to provide confirmatory testing however should include the option in employee's rights.[22] The consequences of false positive results are substantial as they may preclude employment or result in termination.

Other Considerations

False negatives may also occur with urine drug monitoring for a variety of reasons. Some of the common causes for false negatives include when the urine is dilute, the urine drug concentration falls below the predetermined cut-off, or when timing of ingestion of the substance in question is beyond the kit's usefulness. Another important consideration is the varying antibodies amongst the different kits. While the immunoassay technology is virtually the same, the antibodies for each tested substance varies; what may return positive for one kit may return negative for another. These reasons highlight the need for confirmatory testing with chromatographic methods.

Role of the Pharmacist and Pharmacy Technician

This is not an exhaustive review of all the pitfalls associated with urine drug monitoring; however, this article highlights the importance of confirmatory testing with GC/MS, LC-MS/MS, or HPLC and reiterates the low specificity associated with urine drug monitoring. False results may delay correct diagnosis and subsequently delay appropriate treatment. Without automatic, confirmatory lab testing, misinterpretation of false results may have significant consequences for a person's workplace, living situation, ability to play sports, and medical insurance coverage. Pharmacists and pharmacy technicians should obtain and thoroughly review a patients' dietary and medication history prior to urine drug monitoring. Pharmacists need to be aware of interfering medications to appropriately counsel patients prior to testing and for proper result interpretation.

Pharmacists play a vital role in educating patients on proper test kit usage and interpretation of results. False positive results should be confirmed with more accurate laboratory testing and is an important counseling point. Many manufacturers provide instructions for sending the same sample for further testing. The patient typically pays for shipping costs and receives results through a website. Confirmatory test results are commonly available within 1 to 2 weeks after the sample is received.

The National Institute on Drug Abuse (https://www.drugabuse.gov/) is a great resource for pharmacists to better understand drug abuse and misuse and how to counsel patients. Patients can also be referred to findtreatment.gov if a treatment facility is desired.

Conclusion

Urine drug monitoring is now easily accessible, inexpensive, and provides patients a convenient method to test use of prescription and illicit drugs. Despite these advantages, a lack of specificity and susceptibility to drug interactions limits its use. An understanding of these limitations by pharmacists and pharmacy technicians is critical when interpreting results and educating patients on proper use of these products.

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Active Learning Patient Case

A worried parent who recently purchased an OTC urine home drug testing kit appears at your pharmacy window and requests a consult. She states she recently bought the home drug testing kit test for her 19 year-old son, WJ, with established addictions to heroin and cannabis. WJ has no other significant past medical history, has no recent fill history at your pharmacy, and Mom is listed as Power of Attorney. Per parent, WJ previously underwent a medically-supervised opioid withdrawal in 2020, refuses subsequent medication treatment, but continues with regular meetings with his therapist. She states WJ smokes nicotine cigarettes but has been adamant that he is not using any other drugs. She is gravely concerned that her son's urine test came back positive for PCP and wishes to discuss the accuracy of the kit.

1. **Which of the following answers do you provide:**
   a. This is not within the scope of practice for pharmacists and needs immediate evaluation by your son's provider.
   b. Home drug-testing kits are quantitative tests that are highly accurate and specific, correctly detecting trace amounts of illegal drugs.
   c. Urine tests are qualitative and should always be confirmed by secondary testing. While they are sensitive, they are not specific; there is a possibility of false positives and negatives.
   d. OTC urine tests are not FDA-regulated and should not be used for the purposes of detecting the use of illegal drugs.

You look online for instructions for returning the sample to the manufacturer's laboratory for follow-up testing by gas chromatography / mass spectroscopy and print them out for your customer. In the meantime, you ask for a thorough medication reconciliation and update patient's profile to include the following medications:

Ibuprofen 400mg PO Q6H PRN headaches, pain

Fluticasone propionate 2 sprays in each nostril Q Day PRN seasonal allergies

Dextromethorphan IR 30mg PO Q3H PRN cough

2. **Two weeks later, she returns thanking you for your time and explains that follow-up testing did not detect PCP. Which of the following is the most appropriate follow-up?**
   a. You try to ascertain the etiology of the cough and provide OTC recommendations, as appropriate.
   b. Warn customer that nicotine cigarettes may cause false positives for THC in urine drug tests and continuing to test with home kits may come back falsely positive.
   c. Explain that higher-than-prescribed doses (200+ mg per day) of dextromethorphan can be abused to achieve euphoria. At these high doses, urine drug monitoring will typically come up positive for PCP in urine tests but negative with GC/MS follow-ups. Patient's dextromethorphan use should be monitored and evaluated.
   d. Inform patient that you are available for assistance with any future OTC drug kit questions.

CONTINUING EDUCATION QUIZ

Note: Instructions for obtaining your CE has changed. Please contact MPhA Headquarters if you have any questions.

The Virginia Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

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Release Date: 11/10/21

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The authors have no financial disclosures to report.

This program is Knowledge Based — acquiring factual knowledge that is based on evidence as accepted in the literature by the health care professionals.

Directions for taking this issue's quiz:

To receive CE credit for this activity, participants must read the article in its entirety, complete an evaluation survey on the activity, and earn a grade of 70% or higher on a short exam.

This issue's quiz on **Common Drug Interactions with Urine Drug Monitoring** can be found online by scanning the code below or go to https://www.lecturepanda.com/r/UrineMonitoring:

(1) Enter your name and contact information.

(2) Take the quiz and click "Complete Quiz."

Explained Answers (Patient Case)

1. **Answer C**
   a. Answer C is correct. A) is incorrect because pharmacists are in a unique position to educate patients about the use of OTC home urine drug monitoring. B) is incorrect because home drug-testing kits are qualitative, not quantitative. Additionally, they are not specific though highly sensitive. D) is incorrect because they are FDA-regulated.

2. **Answer C**
   a. Answer C is correct. A) and D) are not wrong however not the most appropriate considering the risk of abuse in the setting of a patient with an established substance abuse disorder. B) Nicotine cigarettes are not known to cause false positives for THC.

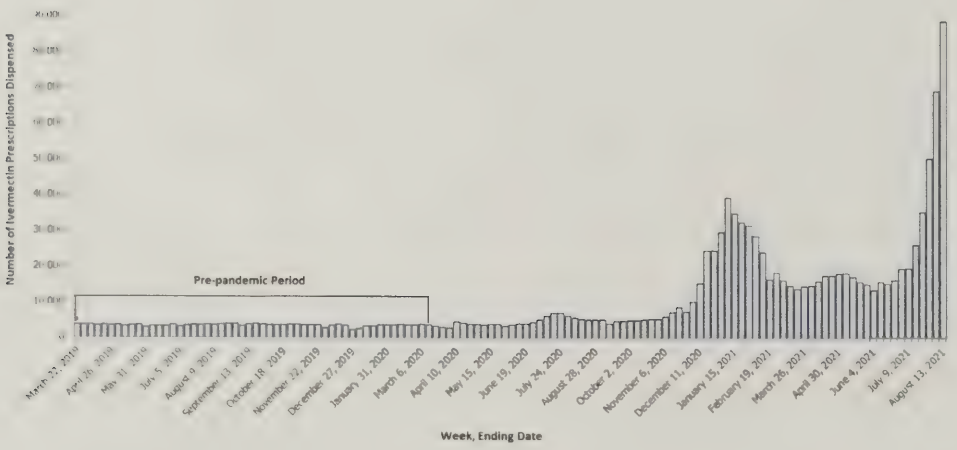
Editorial

Audit Risk: Ivermectin Used for Treating COVID-19

By Trenton Thiede, PharmD, MBA, President at PAAS National®, expert third party audit assistance and FWA/HIPAA compliance.

Ivermectin has been getting a lot of press as of late, from news outlets, national associations, and federal agencies, regarding the dangers of using it to treat or prevent COVID-19. While many of the reports discuss the concern about using veterinary products, there are also many reports of adverse effects when using high, and unauthorized or unapproved, doses of human products.

In March of 2021, the FDA published an article titled Why You Should Not Use Ivermectin to Treat or Prevent COVID-19 which lays out some of the reasons it is currently considered an ill-advised treatment, including not being an anti-viral drug, potential for serious patient harm when taken in large doses, and potential for patients to access via illegitimate sources and/or medications intended for animals. Subsequently, the CDC issued an official health advisory on August 26 to remind both clinicians and the public about the lack of evidence to support ivermectin use for COVID-19 and the potential dangers. Despite the FDA warning, the CDC advisory indicated a 24-fold increase in the number of outpatient prescriptions being prescribed, compared to the pre-pandemic baseline.



Consequently, PAAS National® is seeing more PBM audits on ivermectin prescriptions. Pharmacies should be prepared to have claims looked at for potential recoupment on the basis of "clinical appropriateness". Pharmacists should give extra scrutiny to telemedicine prescribers who may not have a valid patient-provider relationship, be prescribing outside their scope of practice, or not licensed in the state in which the patient resides.

Due to the exponential increase in prescribing and dispensing, the AMA, APhA and ASHP issued a joint press release on September 1, 2021 calling for an immediate end to the prescribing, dispensing, and use of ivermectin for COVID-19 outside of clinical trials.

PAAS Tips:

- PAAS Audit Assistance members can view the July 2021 Article, Audit Risk: Ivermectin Used for Treating COVID-19 on portal.paasnational.com
- Prescriptions successfully processed at point-of-sale do not guarantee payment. PBMs, and payers, use pay and chase methods to recoup claims to avoid inhibiting potentially needed access to medications.
- Prescriptions dispensed for cash may still carry risk (outside the scope of PAAS audit services).
  - While off-label prescribing is commonplace, what is atypical with ivermectin treatment for COVID is the FDA, CDC, NIH, and National Medical and Pharmacy Organizations recommending against its utility. Consequently, this seems to open the door for potential malpractice lawsuits to occur.
  - At face value, would a prescription be considered reasonable in the face of the aforementioned opposition, or does the pandemic environment and a pharmacist's experience and professional judgement supersede?

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Editorial

Electronic Prescriptions – Quantity Unit of Measure

By Trenton Thiede, PharmD, MBA, President at PAAS National®, expert third party audit assistance and FWA/HIPAA compliance.

Electronic prescriptions (or e-prescriptions) are becoming more commonplace every year, and this has brought new types of communication errors and audit risks. While e-prescriptions have greatly improved communication between prescribers and pharmacies by removing errors with handwriting and legibility, there are continued issues with ambiguity, often related to the prescribed quantity.

The PAAS National® Analyst team reviews hundreds of e-prescriptions each day and sees the same problems that your pharmacy experiences when interpreting these prescriptions. We also see the results from PBM audits when these same prescriptions are marked discrepant due to "overbilled quantity" or "invalid hardcopy" – most often when the unit of measure on the e-prescription is ambiguous, mismatched with the prescribed drug or making no sense.

The most problematic "unit of measure" examples include:

NCPDP Preferred Term	NCIt Code
Unspecified	C38046
Bottle	C48477
Box	C48478
Unspecified	C48549

E-prescriptions use a standardized code set to communicate prescription information to pharmacies – this is called the NCPDP SCRIPT Standard. This standard is updated every few years to make improvements and the most recent "upgrade" from NCPDP SCRIPT Standard v10.6 to v2017071 was supposed to go into effect January 1, 2020; however, it was delayed due to the COVID-19 pandemic. Surescripts has reported they will "sunset" v10.6 on September 1, 2021 the values for Bottle, Box, and Tube will no longer be available to prescribers after this date. Pharmacies will still want to be on the lookout for e-prescriptions with unit of measure "unspecified."

Example:

When receiving e-prescriptions with quantity of "1 unspecified," you should assume this is the smallest commercial package size, unless otherwise specified. PAAS has even seen Humana recoup when a pharmacy dispensed 15 mL of Lantus® SoloStar® when the e-prescription said "15 unspecified" and the quantity was not clarified - incredulous!

PAAS advises that pharmacies contact the prescriber's office to clarify and make a clinical notation to ensure you are dispensing the intended quantity and reduce audit risk. While these calls may be annoying (to both parties), they provide a valuable feedback mechanism to the prescriber's office of how these prescriptions are being received. A reminder that good clinical notations should include four elements:

1. Who you spoke to at the prescriber office (including their title)
2. The date you spoke with them
3. What you spoke about
4. Your initials

PAAS Tips:

- The "best" units of measure include: Gram (C48155), Milliliter (C28254), Each (C64933)
- Surescripts has an Independent Pharmacy Helpline where they can work with both prescribers and pharmacy software vendors to resolve "bad e-prescriptions"
- See NCPDP's SCRIPT Implementation Recommendations May 2021, Section 13 for further discussion about Quantity Unit of Measure

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Editorial

Pharmacy and the Law

Drug Recalls

By Don R. McGuire Jr., R.Ph., J.D., General Counsel, Senior Vice President, Risk Management & Compliance at Pharmacists Mutual Insurance Company.

As a young pharmacist, I experienced my first recall when the drug Oraflex (benoxaprofen) was taken off the market in 1982. The drug was effective in treating arthritis, but had some serious side effects. What I remember were patients telling us this was the only drug that worked for them and asking us to sell it to them rather than returning the drug to the manufacturer. Ultimately, we decided to send it back to the manufacturer. The recent recall of ranitidine and other products for nitrosamine impurities caused me to reflect on how little I understood recalls in 1982.

Drug recalls are voluntary actions taken by a manufacturer to remove a defective product from the marketplace. A recall can be initiated by the manufacturer or the Food and Drug Administration (FDA) can request a recall. Recalls are almost always voluntary by the manufacturer and FDA rarely requests a recall. FDA's role in a drug recall is the same as in the recall of other FDA regulated products; e.g. medical devices, cosmetics, food, etc. The agency's role is to classify the recall, to oversee the manufacturer's strategy, and assess the adequacy of the recall.

Recalls are classified by their severity. Class I recalls involve a dangerous or defective product that could cause serious health problems or death. Class II recalls involve products that could cause a temporary health problem or a slight threat of serious harm. Products involved in Class III recalls are unlikely to cause adverse health reactions, but the products violate labeling or manufacturing laws. You will not hear about every recall on the news. Public notification of a recall usually occurs when the product has been widely distributed or poses a serious health hazard, such as in a Class I recall. However, all recalls are posted weekly on the FDA website through their Enforcement Reports page. (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports) You can also register to receive email notifications of new and updated recalls. Familiarizing yourself with current recalls will be beneficial when your patients contact you with a question about a recall. FDA recommends patients talk to their pharmacists about recalled medications. Class I recalls generally provide information specifically for patients, but other Class recalls

do not. Being informed about current recalls will assist you in helping your patients get replacement therapies.

The ranitidine recall applied to both prescription and over-the-counter (OTC) versions of the drug. The recall notice advised patients to stop taking OTC ranitidine immediately, but to consult with their health care professional about other treatment options before discontinuing prescription ranitidine. These types of instruction will generate questions from your patients. Besides being aware of the recommendations for your patients, the recall notice will advise the pharmacy on the removal of the drug from stock and the return procedures.

From a liability perspective, you should follow the procedures outlined in the recall notice. Remove items from stock as instructed. Some recalls will advise you to contact patients currently taking a prescription product. Verify that you have or had the affected lots and notify your patients who received the affected lots as soon as practical. Keeping your computer system updated with current lot numbers and expiration dates of prescription products is crucial to being able to identify those who have received the recalled product. If you receive a new prescription after the recall notice, use the opportunity to help educate prescribers in your area. Be ready to suggest alternatives that are not affected by the recall. Needless to say, it is not a good idea to sell or dispense recalled products at the patient's request instead of following the return process in the recall notice. Another bad idea is compounding the recalled medication when the manufactured product isn't available due to a recall.

Rather than being a passive recipient of information, going online to regularly review recall notices will allow you to be proactive with you patients' therapies. Your patients will see you as a trusted partner in their healthcare. Follow the recall procedures, make sound professional judgments when necessary, and your patients will value your services even more.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

MPhA

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Executive Directors Message

As we closed out Pharmacists Month, I was so pleased to be able to host and attend live events and see all the activities taking place in communities around the state and on our school campuses that highlighted the impact of Maryland pharmacy. MPhA received commendations and proclamations from national, state, and local elected officials who recognize the service our members provide to Marylanders. They also highlighted the role MPhA plays in strengthening the profession; advocating for changes in the profession; and promoting our membership's excellent contributions to better public health. Check out any of our social media pages to see the beautiful documents!

Over the last year MPhA leadership has looked at who and what we are today and what we want our future to be. I am truly excited about the work that has been put in to create a strategic plan for the next steps in MPhA's future. It's time for REINVENTION. It requires finding the right balance between innovation and tradition, while recognizing the social, technological, economic, and clinical environment of our membership. COVID, workforce conditions, and shifts in the professional marketplace have changed your realities and MPhA's relevance. The Board has taken your feedback from surveys, townhall discussions, committee input and one-on-one conversations with students, new practitioners, and seasoned professionals to set a strategic foundation that will lead us to our needed reinvention. The primary goals of the strategic plan are to: 1) expand pharmacy practice; 2) drive diversity, equity, and inclusion in Maryland pharmacy; and 3) ensure financial health and longevity of the association. Those goals are straightforward, but given the environment, we must fundamentally change how we get there. The Board looks forward to sharing the process for achieving the goals and is committed to reporting the progress.

Aliyah Horton at University of Maryland School of Pharmacy - Advocacy Hour during American Pharmacists Month.

I back up President Chris Charles in encouraging you get involved in a committee or consider running for a volunteer leader position to assist MPhA in remaining relevant and impactful for Maryland pharmacy community today and in the future.

All the best,

Aliyah N. Horton, CAE
Executive Director

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- Eligible students must plan to practice in one of the following settings:
  - an independent or small chain community pharmacy, or
  - an underserved geographic or cultural community, preferably in an independent or small chain community pharmacy

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